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Consolidated Guidance About Materials Licenses

Program-Specific Guidance About Medical Use Licenses

Final Report

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Prepared by
P.A. Lanzisera, A.R. Jones, R.G. Gattone, R.D. Reid

Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

ABSTRACT

As part of its redesign of the materials licensing process, the United States Nuclear Regulatory Commission (NRC) is consolidating and updating numerous guidance documents into a single comprehensive repository as described in NUREG-1539, "Methodology and Findings of the NRC's Materials Licensing Process Redesign," dated April 1996, and draft NUREG-1541, "Process and Design for Consolidating and Updating Materials Licensing Guidance," dated April 1996. NUREG-1556, Vol. 9, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Medical Use Licenses," dated July 2001, is the ninth program-specific guidance document developed for the new process and is intended for use by applicants, licensees, and NRC staff and will also be available to Agreement States. This guidance document corresponds to the revised Code of Federal Regulations (CFR), Title 10, Part 35, "Medical Use of Byproduct Material," published as a final rule at **[insert Federal Register Notice and Date]**. This document combines and supersedes the guidance previously found in: Regulatory Guide (RG) 10.8, Revision 2, "Guide for the Preparation of Applications for Medical Use Programs"; Appendix X to RG 10.8, Revision 2, "Guidance on Complying With New Part 20 Requirements"; Draft RG DG-0009, "Supplement to Regulatory Guide 10.8, Revision 2, Guide for the Preparation of Applications for Medical Use Programs"; Draft RG FC 414-4, "Guide for the Preparation of Applications for Licenses for Medical Teletherapy Programs"; Policy and Guidance Directive (P&GD) FC 87-2, "Standard Review Plan for License Applications for the Medical Use of Byproduct Material"; P&GD FC 86-4, Revision 1, "Information Required for Licensing Remote Afterloading Devices"; Addendum to Revision 1 to P&GD FC 86-4, "Information Required for Licensing Remote Afterloading Devices-Increased Source Possession Limits"; P&GD 3-15, "Standard Review Plan for Review of Quality Management Programs"; RG 8.39, "Release of Patients Administered Radioactive Materials"; RG 8.33, "Quality Management Program"; P&GD 3-17, "Review of Training and Experience Documentation Submitted by Proposed Physician User Applicants"; and RG 8.23, "Radiation Safety Surveys at Medical Institutions, Revision 1."

Consistent with the revised regulations, this guidance provides, where applicable, a more risk-informed, performance-based approach to medical use licensing. This approach also reduces the detailed information that medical applicants must submit in support of an application for medical use of byproduct material.

CONTENTS

APPENDICES

FIGURES

TABLES

CONTENTS

FOREWORD

NRC is using Business Process Redesign (BPR) techniques to redesign its materials licensing process. This effort is described in NUREG-1539, "Methodology and Findings of the NRC's Materials Licensing Process Redesign," dated April 1996. A critical element of the new process is consolidating and updating numerous guidance documents into a NUREG-series of reports. Below is a list of volumes currently included in the NUREG-1556 series:

Vol. No.	Volume Title	Status
1	Program-Specific Guidance About Portable Gauge Licenses	Final Report
2	Program-Specific Guidance About Industrial Radiography Licenses	Final Report
3	Applications for Sealed Source and Device Evaluation and Registration	Final Report
4	Program-Specific Guidance About Fixed Gauge Licenses	Final Report
5	Program-Specific Guidance about Self-Shielded Irradiator Licenses	Final Report
6	Program-Specific Guidance about 10 CFR Part 36 Irradiator Licenses	Final Report
7	Program-Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope	Final Report
8	Program-Specific Guidance about Exempt Distribution Licenses	Final Report
9	Program-Specific Guidance about Medical Use Licenses	Final Report
10	Program-Specific Guidance about Master Materials Licenses	Final Report
11	Program-Specific Guidance about Licenses of Broad Scope	Final Report
12	Program-Specific Guidance about Possession Licenses for Manufacturing and Distribution	Final Report
13	Program-Specific Guidance about Commercial Radiopharmacy Licenses	Final Report
14	Program-Specific Guidance about Well Logging, Tracer, and Field Flood Study Licenses	Final Report

Vol. No.	Volume Title	Status
15	Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses	Final Report
16	Program-Specific Guidance About Licenses Authorizing Distribution To General Licensees	Final Report
17	Program-Specific Guidance About Licenses for Special Nuclear Material of Less Than Critical Mass	Final Report
18	Program-Specific Guidance About Service Provider Licenses	Final Report
19	Guidance For Agreement State Licensees About NRC Form 241 "Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters" and Guidance For NRC Licensees Proposing to Work in Agreement State Jurisdiction (Reciprocity)	Final Report
20	Guidance About Administrative Licensing Procedures	Final Report

This document, NUREG-1556, Vol. 9, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Medical Use Licenses," dated July 2001, is the ninth program-specific guidance document developed for the new process. It is intended for use by applicants, licensees, NRC license reviewers, and other NRC personnel. It combines and updates the guidance for applicants and licensees previously found in RG 10.8, Revision 2, "Guide for the Preparation of Applications for Medical Use Programs," dated August 1987, and the guidance for licensing staff previously found in P&GDs, draft RGs, and Standard Review Plans. In addition, this report also contains pertinent information found in Information Notices (INs), as listed in Appendix A.

Because this report takes a risk-informed, performance-based approach to medical use licensing, it reduces the amount of information needed from an applicant seeking to possess and use certain quantities of byproduct material. For instance, the regulations found in 10 CFR Part 35 and reflected in this report do not require the submission of detailed radiation monitoring equipment calibration procedures. Instead, confirmation of the development of procedures in accordance with the regulations is requested.

A team composed of NRC and state departments of health staff drafted this document, drawing on their collective experience in radiation safety in general and as specifically applied to medical use of byproduct material. A representative of NRC's Office of the General Counsel provided legal guidance.

NUREG-1556, Vol. 9, is not a substitute for NRC regulations. The approaches and methods described in this report are provided for information only.

Donald A. Cool, Director
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards

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The Participants

Brown, Carrie
Bolling, Lloyd A.
Cool, Donald A.
DelMedico, Joseph R.
Euchner, Jennifer
Flack, Diane S.
Haney, Catherine
Hill, Thomas E.
Howard, Marcia
Jones, Samuel Z.
Lohaus, Paul H.
Lieberman, James
Merchant, Sally L.
Paperiello, Carl A.
Rothschild, Marjorie U.
Roe, Mary Louise
Siegel, M.D., Barry
Taylor, Torre M.
Trottier, Cheryl A.
Treby, Stuart A.
Walter, David
Woods, Susanne R.
Young, Thomas F.

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Ayers, Robert
Bhalla, Neelam
Brown, Carrie
Brown, Keith D.
Frazier, Cassandra F.
Fuller, Mike L.
Holahan, Patricia K.
Merchant, Sally L.
Minnick, Sheri A.
Schlueter, Janet R.
Smith, James A.
Taylor, Torre M.

ABBREVIATIONS

AAPM	American Association of Physicists in Medicine
ACMUI	Advisory Committee on the Medical Use of Isotopes
ALARA	as low as is reasonably achievable
ALI	annual limit on intake
AMP	Authorized Medical Physicist
ANP	Authorized Nuclear Pharmacist
ANSI	American National Standards Institute
AU	Authorized User
bkg	background
BPR	Business Process Redesign
Bq	Becquerel
CFR	Code of Federal Regulations
Ci	Curie
cc	centimeter cubed
cm^2	centimeter squared
Co-57	cobalt-57
Co-60	cobalt-60
cpm	counts per minute
Cs-137	cesium-137
DAC	derived air concentration
DIS	decay-in-storage
DOT	United States Department of Transportation
dpm	disintegrations per minute
FDA	United States Food and Drug Administration
ft	foot
GM	Geiger-Mueller
GPO	Government Printing Office

GSR	gamma stereotactic radiosurgery
HDR	high dose-rate
I-125	iodine-125
I-131	iodine-131
IN	Information Notice
IP	Inspection Procedure
Ir-192	iridium-192
LDR	low dose-rate
mCi	millicurie
ml	milliliter
mR	milliroentgen
mrem	millirem
mSv	millisievert
NaI(Tl)	sodium iodide (thallium doped)
NCRP	National Council on Radiation Protection and Measurements
NIST	National Institute of Standards and Technology
NRC	United States Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
OCFO	Office of the Chief Financial Officer
OCR	optical character reader
OMB	Office of Management and Budget
OSL	optically stimulated luminescence dosimeters
P-32	phosphorus-32
Pd-103	palladium-103
PDR	pulsed dose-rate
P&GD	Policy and Guidance Directive
QA	quality assurance
Ra-226	radium-226

RG	Regulatory Guide
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
SDE	shallow-dose equivalent
SI	International System of Units (abbreviated SI from the French Le Système Internationale d'Unites)
Sr-90	strontium-90
SSDR	Sealed Source and Device Registration
std	standard
Sv	Sievert
TAR	Technical Assistance Request
Tc-99m	technetium-99m
TEDE	total effective dose equivalent
TLD	thermoluminescent dosimeters
U-235	uranium-235
WD	written directive
μCi	microcurie
%	percent

1 PURPOSE OF REPORT

The term "patient" is used to represent "patient" or "human research subject" throughout this report. The term "applicant" is used when describing the application process and the term "licensee" is used when describing a regulatory requirement.

This report provides guidance to an applicant in preparing a medical use license application. It also provides guidance on NRC criteria for evaluating a medical use license application. It is not intended to address the commercial aspects of manufacturing, distribution, and service of sources in devices. Additionally, since this report gives guidance for applying for an application under 10 CFR Part 35, "Medical Use of Byproduct Material," it does not specifically describe the possession and use of pacemakers, which are licensed under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material."

Radionuclides are used for a variety of purposes in medicine. Typical uses are:

- Diagnostic studies with unsealed radionuclides;
- Therapeutic administrations with unsealed radionuclides;
- Diagnostic studies with sealed radionuclides;
- Manual brachytherapy with sealed sources;
- Therapeutic administrations with sealed sources in devices (i.e., teletherapy, remote afterloaders, and gamma stereotactic radiosurgery (GSR) units).

This report describes the information needed to complete NRC Form 313 (Appendix B), "Application for Material License," for medical use of radionuclides. This guidance volume (NUREG-1556, Vol. 9) may not directly address complete radiation safety and licensing guidance for uses specified in 10 CFR 35.1000. Therefore, NRC staff should be contacted with questions regarding licensing information for such uses. The information collection requirements in 10 CFR Parts 30 and 35 and NRC Form 313 have been approved under the Office of Management and Budget (OMB) Clearance Numbers 3150-0017, 3150-0010, and 3150-0120, respectively.

The format within this document for each item of technical information is as follows:

- **Regulations** – references the regulations applicable to the item;
- **Criteria** – outlines the criteria used to judge the adequacy of the applicant's response;

- **Discussion** – provides additional information on the topic sufficient to meet the needs of most readers; and
- **Response from Applicant** – provides suggested response(s) or indicates that no response is needed on that topic during the initial licensing process.

The regulations require the applicant and/or licensee to develop, document, and implement procedures that will ensure compliance with the regulations. The appendices describe model radiation protection procedures. Each applicant should read the regulations and model procedures carefully and then decide if the model procedure addresses specific radiation protection program needs at the applicant's facility. Applicants may adopt a model procedure or they may develop their own procedures to comply with the applicable regulation. Except for procedures required by Subpart H of 10 CFR Part 35, written procedures developed by applicants do not need to be submitted as part of the license application. However, the applicant must state that applicable procedures have been developed, implemented, and maintained in accordance with the regulations.

NRC Form 313 does not have sufficient space for applicants to provide full responses to Items 5 through 11; as the form indicates, answers to those items must be provided on separate sheets of paper and submitted with the completed NRC Form 313.

Appendix C includes:

- Sample medical licenses with conditions most often found in these licenses (not all licenses will have all conditions);
- A checklist to assist the applicant in determining which sections of this document and required procedures apply to the type of medical license requested;
- A checklist for providing application information.

Appendix C contains a sample license for pacemakers. However, as described above, this document provides guidance only on medical use of byproduct material, and does not specifically address the possession and use of pacemakers. Appendices D through Y contain additional information on various radiation protection topics.

In this document, "dose" or "radiation dose" means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent (TEDE). These terms are defined in 10 CFR Part 20. Rem, and Sievert (Sv), its SI equivalent (1 rem = 0.01 Sv), are used to describe units of radiation exposure or dose. These units are used because 10 CFR Part 20 sets dose limits in terms of rem, not rad or roentgen. Furthermore, the sources commonly used in therapy emit beta and photon radiation,

and as 10 CFR Part 20 states, the quality factor of 1 is applied for high-energy beta emissions and photons, resulting in the following relation: 1 roentgen = 1 rad = 1 rem.

This NUREG not only updates the information and guidance provided in Revision 2 of RG 10.8, "Guide for the Preparation of Applications for Medical Use Programs," but also revises the format in which it is presented to assist with the preparation of a medical use license. Revision 2 was issued in August 1987 to provide guidance for the revised 10 CFR Part 35, which became effective April 1, 1987. Since then, 10 CFR Part 35 has been amended a number of times. Technology-specific information has been revised and expanded to include technologies that are now more commonly used, for example, computerized remote afterloading brachytherapy and gamma stereotactic radiosurgery (GSR).

Applicants and licensees should also be aware of two other documents that provide useful information for medical use licensees. The first is NUREG-1556, Volume 11, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope," dated April 1999, which provides additional licensing guidance on medical use programs of broad scope. The second document is NUREG-1516, "Effective Management of Radioactive Materials Safety Programs at Medical Facilities," dated May 1997. The guidance in NUREG-1516 emphasizes a team approach to program management as a means to effectively manage radiation protection programs, and provides tools to help licensees manage these programs. Radiation protection team members should include the management of the licensed facility, the Radiation Safety Committee (RSC), if applicable, and the Radiation Safety Officer (RSO). The document also describes the duties and responsibilities of the RSO and supervised individuals, conduct of required audits, advantages and disadvantages in using consultants or service companies to augment the radiation protection program, resources that may be needed to support the program, and NRC notification and reporting requirements. However, changes in 10 CFR Part 35 may make the description of notification and reporting requirements found in NUREG-1516 obsolete. Specific tools for day-to-day operation of a radiation protection program are provided in several appendices in NUREG-1516. Additionally, an extensive annotated bibliography lists publications on radiation protection program management at medical facilities.

1.1 LICENSES

NRC regulates the intentional internal or external administration of byproduct material, or the radiation from byproduct material, to patients or human research subjects for medical use. A specific license of either limited or broad scope is issued to authorize possession and use of licensed material. These licenses are issued pursuant to 10 CFR Parts 30, 33, and 35. NRC issues three types of licenses for the use of byproduct material in medical practices and facilities. These are the general *in vitro* license, the specific license of limited scope, and the specific license of broad scope.

NRC usually issues a single byproduct material license to cover an entire radionuclide program – except for nuclear-powered pacemakers. A license including teletherapy may also contain the authorization for source material (i.e., depleted uranium) used as shielding in many teletherapy units. Although NRC may issue separate licenses to individual licensees for different medical uses, it does not usually issue separate licenses to different departments in a medical facility or to individuals employed by or with whom the medical facility has contracted. Only the facility's management may sign the license application.

Applicants should study this report, related guidance, and all applicable regulations carefully before completing NRC Form 313. NRC expects licensees to provide information on specific aspects of the proposed radiation protection program in attachments to NRC Form 313. When necessary, NRC may ask the applicant for additional information in order to gain reasonable assurance that an adequate radiation protection program has been established. Additionally, guidance on use at multiple sites can be found in P&GD PG 1-23, "Guidance for Multi-Site Licenses."

After a license is issued, the licensee must conduct its program in accordance with the following:

- Statements, representations, and procedures contained in the application and in correspondence with NRC;
- Terms and conditions of the license;
- NRC regulations.

In 10 CFR 30.9, NRC requires that the information in the application be complete and accurate in all material respects. Information is considered material if it has the ability to change or affect an agency decision on issuing the license.

1.1.1 GENERAL *IN VITRO* LICENSE

In 10 CFR 31.11, "General License for Use of Byproduct Material for Certain *In Vitro* Clinical or Laboratory Testing," NRC establishes a general license authorizing physicians, veterinarians, clinical laboratories, and hospitals to receive, acquire, possess, or use small quantities of certain byproduct material for *in vitro* clinical or laboratory tests not involving "medical use" (i.e., not involving administration to humans). Section 31.11 explains the requirements for using the materials listed. If the general license alone meets the applicant's needs, only NRC Form 483, "Registration Certificate – *In Vitro* Testing With Byproduct Material Under General License," need be filed. Medical-use licensees authorized pursuant to 10 CFR Part 35 do not need to file the form.

NRC limits possession to a total of 200 microcuries of photon-emitting materials listed in 10 CFR 31.11 at any one time, at any one location of storage or use. The use of materials listed in 10 CFR 31.11 within the inventory limits of that section is subject only to the requirements of that section and not to the requirements of 10 CFR Parts 19, 20, and 21, except as set forth in 10 CFR 31.11.

An applicant needing more than 200 microcuries of these materials must apply for a specific license and may request the increased inventory limit as a separate line item on NRC Form 313. This type of applicant generally requests an increased limit of 3 millicuries. If requesting an increased inventory limit, the applicant will be subject to the requirements of 10 CFR Parts 19, 20, and 21, including the requirements for waste disposal.

1.1.2 SPECIFIC LICENSE OF LIMITED SCOPE

NRC issues specific medical licenses of limited scope to private or group medical practices and to medical institutions. A medical institution is an organization in which more than one medical discipline is practiced. In general, individual physicians or physician groups located within a licensed medical facility (e.g., hospital) may not apply for a separate license because 10 CFR 30.33(a)(2) refers to the applicant's facilities. Since a physician group does not normally have control over the facilities, the hospital remains responsible for activities conducted on its premises and must apply for the license. On specific licenses of limited scope, the authorized users are specifically listed in the license.

Byproduct material may be administered to patients on an inpatient (i.e., hospitalized) or outpatient basis. For patients to whom byproduct material is administered and who are not releasable under 10 CFR 35.75, inpatient facilities are required. In general, facilities for private and group practices do not include inpatient rooms and, therefore, procedures requiring hospitalization of the patient under 10 CFR 35.75 cannot be performed.

A specific license of limited scope may also be issued to an entity requesting to perform mobile medical services (10 CFR 35.80, 10 CFR 35.647). A medical institution or a private or group practice may apply for authorization to use byproduct material in a mobile medical service.

1.1.3 SPECIFIC LICENSE OF BROAD SCOPE

Medical institutions that provide patient care and conduct research programs that use radionuclides for *in vitro*, animal, and medical procedures may request a specific license of broad scope in accordance with 10 CFR Part 33. The criteria for the various types of broad scope licenses are found in 10 CFR 33.13 through 10 CFR 33.17. Generally, NRC issues specific licenses of broad scope for medical use (i.e., licenses authorizing multiple quantities and types of

byproduct material for unspecified uses) to institutions that (1) have experience successfully operating under a specific license of limited scope; and (2) are engaged in medical research and routine diagnostic and therapeutic uses of byproduct material. NUREG-1556, Vol. 11, offers additional guidance to applicants for a specific license of broad scope.

1.2 THE 'AS LOW AS IS REASONABLY ACHIEVABLE (ALARA)' CONCEPT

10 CFR 20.1101, "Radiation Protection Programs," states that "each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities …" and "the licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are...ALARA." This section also requires that licensees review the content of the radiation protection program and its implementation at least annually. The RSO is responsible for the day-to-day operation of the radiation protection program.

RG 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures ALARA," and RG 8.18, "Information Relevant to Ensuring That Occupational Radiation Exposures at Medical Institutions Will Be ALARA," provide the NRC staff position on this subject. Several other NRC publications contain background information on the ALARA philosophy and its application in the medical environment. For example, NUREG-0267, "Principles and Practices for Keeping Occupational Radiation Exposures at Medical Institutions ALARA"; NUREG-1134, "Radiation Protection Training for Personnel Employed in Medical Facilities"; and NUREG-1516, "Effective Management of Radioactive Material Safety Programs at Medical Facilities," all contain information, methods, and references useful in establishing radiation protection programs to maintain radiation exposures ALARA in medical facilities. Applicants should consider the ALARA philosophy detailed in these reports when developing plans to work with licensed radioactive materials.

1.3 WRITTEN DIRECTIVE (WD) PROCEDURES

10 CFR 35.41 requires medical use licensees to develop, implement, and maintain written procedures to provide high confidence that before each administration requiring a WD, the patient's identity is verified and the administration is in accordance with the WD. This regulation also specifies what, at a minimum, these procedures must address. Appendix S provides further information on developing these procedures.

1.4 RESEARCH INVOLVING HUMAN SUBJECTS

10 CFR 35.2 defines "medical use" to include the administration of byproduct material to human research subjects. Furthermore, 10 CFR 35.6, "Provisions for the protection of human research subjects" addresses the protection of the rights of human subjects involved in research conducted by limited specific medical use licensees and broad scope medical use licensees.

Prior NRC approval is not necessary if the research is conducted, funded, supported, or regulated by another Federal Agency that has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, the licensee must apply for a specific amendment and receive approval for the amendment before conducting such research. Whether or not a license amendment is required, licensees must obtain informed consent from human subjects and prior review and approval of the research activities by an Institutional Review Board in accordance with the meaning of those terms under the Federal Policy. In accordance with 10 CFR 35.6(a), research involving human subjects shall be conducted only with byproduct materials listed in the license for the uses authorized in the license.

Licensees conducting human research using radioactive drugs, sealed sources, and/or devices are responsible for ensuring that, in addition to complying with 10 CFR 35.6, they comply with all other applicable NRC requirements and license conditions. Therefore, it is a licensee's responsibility to ensure that:

- It is authorized to possess the materials and devices needed to participate in the research studies;
- The materials and devices to be used in the research are included in the specific medical uses authorized in the license;
- The procedures in the research protocols do not conflict with NRC regulatory and license requirements; and
- It is in compliance with 10 CFR 35.6, its license, and any other NRC regulatory requirements.

2 AGREEMENT STATES

Certain states, called Agreement States (see Figure 2.1), have entered into agreements with NRC that give them the authority to license and inspect byproduct, source, or special nuclear materials used or possessed within their borders. Any applicant other than a Federal Agency who wishes to possess or use licensed material in one of these Agreement States needs to contact the responsible officials in that state for guidance on preparing an application. These applications are filed with state officials, not with NRC.

In the special situation of work at Federally-controlled sites in Agreement States, it is necessary to know the jurisdictional status of the land to determine whether NRC or the Agreement State has regulatory authority. NRC has regulatory authority over land determined to be under "exclusive Federal jurisdiction," while the Agreement State has jurisdiction over non-exclusive Federal jurisdiction land. Applicants and licensees are responsible for finding out, in advance, the jurisdictional status of the specific areas where they plan to conduct licensed operations. NRC recommends that applicants and licensees ask their local contacts for the Federal Agency controlling the site (e.g., contract officer, base environmental health officer, district office staff) to help determine the jurisdictional status of the land and to provide the information in writing, so that licensees can comply with NRC or Agreement State regulatory requirements, as appropriate. Additional guidance on determining jurisdictional status is found in All Agreement States Letter, SP-96-022, dated February 16, 1996, which is available from NRC upon request.

Table 2.1 provides a quick way to check on which agency has regulatory authority.

Table 2.1 Who Regulates the Activity?

Applicant and Proposed Location of Work	Regulatory Agency
Federal Agency regardless of location (except that Department of Energy [DOE] and, under most circumstances, its prime contractors are exempt from licensing [10 CFR 30.12])	NRC
Non-Federal entity in non-Agreement State, U.S. territory, or possession	NRC
Non-Federal entity in Agreement State at non-Federally controlled site	Agreement State
Non-Federal entity in Agreement State at Federally-controlled site ***not*** subject to exclusive Federal jurisdiction	Agreement State
Non-Federal entity in Agreement State at Federally-controlled site subject to exclusive Federal jurisdiction	NRC

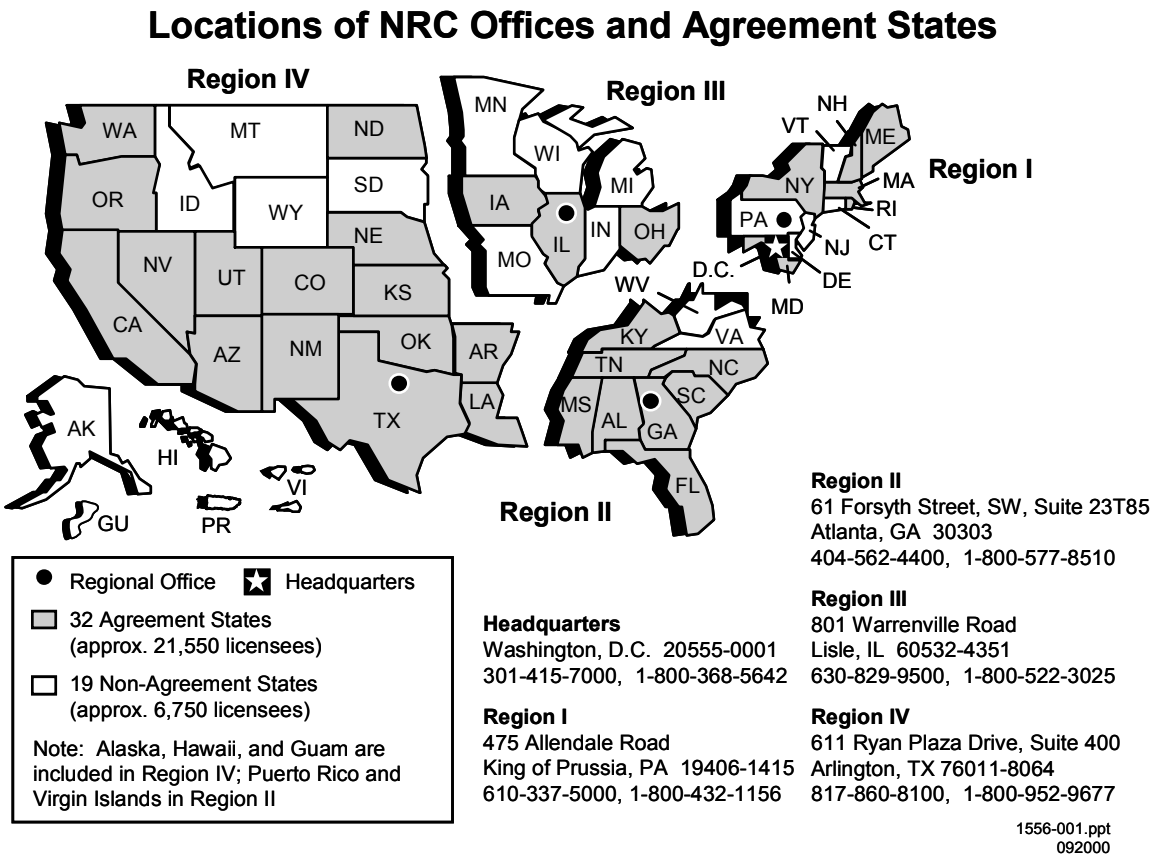

Figure 2.1 U.S. Map. ***Location of NRC Offices and Agreement States.***

Reference: A current list of Agreement States (including names, addresses, and telephone numbers of responsible officials) may be obtained upon request from NRC's Regional Offices. The NRC Office of State and Tribal Programs (STP) also provides the current list of Agreement States at web site <http://www.hsrd.ornl.gov/nrc>, under "Directories" and then under "State Program Directors."

The All Agreement States Letter, SP-96-022, dated February 16, 1996, is available by calling NRC's toll-free number at (800) 368-5642 and asking for STP. STP also provides this information at web site <http://www.hsrd.ornl.gov/nrc>, under "NRC-State Letters."

3 MANAGEMENT RESPONSIBILITY

Regulations: 10 CFR 30.9; 10 CFR 35.12; 10 CFR 35.24.

NRC endorses the philosophy that effective radiation protection program management is vital to safe operations that comply with NRC regulatory requirements (see 10 CFR 35.24).

"Management" refers to the chief executive officer or other individual having the authority to ***manage, direct, or administer the licensee's activities*** or that person's delegate or delegates.

To ensure adequate management involvement in accordance with 10 CFR 35.12(a) and 35.24(a), a management representative (i.e., chief executive officer or delegate) must sign the submitted application acknowledging management's commitments to and responsibility for the following:

- Radiation protection, security, and control of radioactive materials, and compliance with regulations;
- Completeness and accuracy of the radiation protection records and all information provided to NRC (10 CFR 30.9);
- Knowledge about the contents of the license application;
- Compliance with current NRC and United States Department of Transportation (DOT) regulations and the licensee's operating and emergency procedures;
- Provision of adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that patients, the public, and workers are protected from radiation hazards;
- Appointment of a qualified individual who has agreed in writing to work as the RSO;
- Approval of qualified individual(s) to serve as Authorized Medical Physicists (AMPs), Authorized Nuclear Pharmacists (ANPs), and Authorized Users (AUs) for licensed activities.

For information on NRC inspection, investigation, enforcement, and other compliance programs, see "General Statement of Policy and Procedures for NRC Enforcement Actions," NUREG-1600; NRC Inspection Manual, Chapter 2800 "Materials Inspection Program"; and Inspection Procedures in the 87100 series (e.g., 87115-Nuclear Medicine, 87116-Teletherapy, 87118-Brachytherapy, and 87119-Medical Broad Scope); see the Notice of Availability on the inside front cover of this report. NUREG-1600 is also available at NRC's web site, <http://www.nrc.gov>, under "Nuclear Materials," then "Enforcement," "Guidance Documents," or "Current Policy."

4 APPLICABLE REGULATIONS

It is the applicant's or licensee's responsibility to have up-to-date copies of applicable regulations, read them, and abide by each applicable regulation.

The following Parts of 10 CFR Chapter I contain regulations applicable to medical use licensees:

- 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders"
- 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations"
- 10 CFR Part 20, "Standards for Protection Against Radiation"
- 10 CFR Part 21, "Reporting of Defects and Noncompliance"
- 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material"
- 10 CFR Part 31, "General Domestic Licenses for Byproduct Material"
- 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material"
- 10 CFR Part 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material"
- 10 CFR Part 35, "Medical Use of Byproduct Material"
- 10 CFR Part 40, "Domestic Licensing of Source Material"
- 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material" (for pacemaker devices)
- 10 CFR Part 71, "Packaging and Transportation of Radioactive Material"

Part 71 requires that licensees or applicants who transport licensed material or who may offer such material to a carrier for transport must comply with the applicable requirements of the DOT that are found in 49 CFR Parts 170 through 189. For ordering information on the regulations, see the Notice of Availability on the inside front cover of this report.

- 10 CFR Part 150, "Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters Under Section 274"
- 10 CFR Part 170, "Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended"

- 10 CFR Part 171, "Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC."

In addition to the information provided in the Notice of Availability (on the inside front cover of this report), to request copies of the above documents, applicants may call the Government Printing Office (GPO) order desk in Washington, DC at (202) 512-1800. Order the two-volume bound version of Title 10, Code of Federal Regulations, Parts 0-50 and 51-199, from the GPO, Superintendent of Documents, Post Office Box 371954, Pittsburgh, Pennsylvania 15250-7954. You may also contact the GPO electronically through its web site at <http://www.gpo.gov>. Request single copies of the above documents from NRC's Regional or Field Offices (see Figure 2.1 for addresses and telephone numbers). NRC publishes amendments to its regulations in the *Federal Register*. These updates may be requested from the appropriate Regional Office before they are included in the bound version of Title 10. Title 10 is also available at <http://www.nrc.gov>, under "Reference Library," and then "Title 10 of The Code of Federal Regulations."

5 HOW TO FILE

5.1 PAPER APPLICATION

Applicants for an NRC materials license should do the following:

- Be sure to use the most recent guidance in preparing an application;
- Complete NRC Form 313 (Appendix B) Items 1 through 4, 12, and 13 on the form itself;
- Complete NRC Form 313 Items 5 through 11 on supplementary pages, or use Appendix C;
- Provide sufficient detail for NRC to determine that equipment, facilities, training, experience, and the radiation safety program are adequate to protect health and safety and minimize danger to life and property;
- For each separate sheet, other than Appendix C, that is submitted with the application, identify and cross-reference it to the item number on the application or the topic to which it refers;
- Submit all documents, typed, on 8-1/2 x 11-inch paper;
- Avoid submitting proprietary information unless it is absolutely necessary;
- Submit an original, signed application and one copy;
- Retain one copy of the license application for future reference.

As required by 10 CFR 35.12(a), applications must be signed by the applicant's or licensee's management; see Section 8.46, Item 13, on "Certification."

Using the suggested wording of responses in this report will expedite NRC's review.

All license applications will be made available for review by the general public in NRC's Public Document Rooms and electronically at the Public Electronic Reading Room. For more information on the Public Electronic Reading Room, visit <http://www.nrc.gov>. If it is necessary to submit proprietary information, follow the procedure in 10 CFR 2.790. Failure to follow this procedure could result in disclosure of the proprietary information to the public or substantial delays in processing the application. Employee personal information, i.e., home address, home telephone number, social security number, date of birth, and radiation dose information, should not be submitted unless specifically requested by NRC.

NRC's new licensing process will be faster and more efficient, in part, through acceptance and processing of electronic applications at some future date. NRC will continue to accept paper

applications. However, these will be scanned through an optical character reader (OCR) to convert them to electronic format. To ensure a smooth transition to electronic applications, applicants are asked to follow these suggestions:

- Submit printed or typewritten – not handwritten – text on smooth, crisp paper that will feed easily into the scanner;
- Choose typeface designs that are sans serif, such as Arial, Helvetica, Futura, Univers; the text of this document is in a serif font called Times New Roman;
- Use 12-point or larger font;
- Avoid stylized characters such as script, italic, etc.;
- Be sure the print is clear and sharp;
- Be sure there is high contrast between the ink and paper (black ink on white paper is best).

5.2 ELECTRONIC APPLICATION

As the electronic licensing process develops, it is anticipated that NRC may provide mechanisms for filing applications via diskettes or CD-ROM and through the Internet. Additional filing instructions will be provided as NRC implements these new mechanisms. When the electronic process becomes available, applicants may file electronically instead of on paper.

6 WHERE TO FILE

Applicants that wish to possess or use licensed material in any State or U.S. territory or possession subject to NRC jurisdiction must file an application with the NRC Regional Office for the locale in which the material will be possessed and/or used. Section 8.42 and Appendix V provide further information on filing procedures for applicants that wish to perform mobile medical services. Figure 2.1 shows NRC's four Regional Offices and their respective areas for licensing purposes, and identifies Agreement States.

In general, applicants that wish to possess or use licensed material in an Agreement State must file an application with the Agreement State, not NRC. However, if work will be conducted at Federally-controlled sites in Agreement States, applicants must first determine the jurisdictional status of the land in order to determine whether NRC or the Agreement State has regulatory authority. Section 2, "Agreement States," has additional information.

7 LICENSE FEES

Application fees are required for new license applications and some other licensing actions. Each application for which a fee is specified must be accompanied by the appropriate fee. Refer to 10 CFR 170.31 to determine the amount of the fee. NRC will not issue the licensing action before it receives the appropriate payment. Consult 10 CFR 170.11 for information on exemptions from fees. Once technical review has begun, no fees will be refunded. Application fees will be charged regardless of NRC's disposition of an application or the withdrawal of an application.

Most NRC licensees are also subject to annual fees; refer to 10 CFR 171.16. Consult 10 CFR 171.11 for information on exemptions from annual fees and 10 CFR 171.16(c) on reduced annual fees for licensees that qualify as "small entities."

Direct all questions about NRC's fees or completion of Item 12 of NRC Form 313 (Appendix B) to the Office of the Chief Financial Officer (OCFO) at NRC Headquarters in Rockville, Maryland, (301) 415-7554. Information about fees may also be obtained by calling NRC toll-free at (800) 368-5642, extension 415-7554, or by sending e-mail to fees@nrc.gov.

Enter the fee category and the amount of the fee enclosed with the application on NRC Form 313.

8 CONTENTS OF AN APPLICATION

This section explains, item by item, the information requested on NRC Form 313. Items 5 through 11 on the form request specific information about the proposed radiation safety program. To assist the applicant in submitting complete information on these items, the applicable regulations are referenced in the discussion of each item.

Applicants must provide detailed information about the following:

- Proposed facilities and equipment;
- Training and experience of byproduct material users and the RSO;
- Delegation of authority to RSO;
- Financial assurance (if applicable);
- Mobile use of byproduct material (if applicable);
- Procedures required by Subpart H, "Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units" (if applicable).

Additionally, in response to Items 9, 10, and 11, the applicant must provide a commitment to develop, implement, and maintain various procedures to meet the requirements of the applicable regulation. The language used in the Response from Applicant – "develop, implement, and maintain" – was chosen because this language is consistent with language used in 10 CFR 35.41 and 10 CFR 35.610. Responses linked to requirements in 10 CFR Part 20 also include the language "develop, implement, and maintain" even though the language in 10 CFR 20.1101 is "develop, document, and implement" and the language in 10 CFR 20.1906 is "establish, maintain, and retain." To simplify the Response from Applicant and to avoid confusion, the language "develop, implement, and maintain" was chosen for all responses. A requirement or commitment to develop, implement, and maintain written procedures means the licensee will:

- Prepare written procedures and keep them available for reference and for NRC inspection purposes;
- Instruct individuals in the procedures;
- Follow the procedures on a day-to-day basis;
- Verify periodically through observation, records review, or some other audit method, that individuals know the procedures and follow them; and
- Update the procedures as necessary to accommodate changes in the license program, such as the introduction of new diagnosis or treatment methods.

Table 1 in Appendix C is provided to help applicants determine which procedures must be developed, implemented, and maintained for the type of medical use requested. Several appendices in this report present sample procedures that applicants may use in developing their procedures. If a particular item requires the applicant to develop, implement, and maintain a procedure, the applicant may use the following wording in each response section on the application:

> "We have developed and will implement and maintain written procedures for _____ that meet the requirements of 10 CFR _____."

If a particular part of a section does not apply, simply note "NA" for "not applicable." If a particular section applies, but a procedure does not have to be developed, simply note "N" for "no response required." NA, N, or short sentence responses to Items 5 through 10 should run consecutively on one or more sheets separate from responses provided on NRC Form 313. Lengthy responses should be appended as attachments.

As indicated on NRC Form 313 (Appendix B), responses to Items 5 through 11 should be submitted on separate sheets of paper. Applicants may use Appendix C to assist with completion of the application. Applicants should note that using the suggested wording of responses will expedite NRC's review.

8.1 ITEM 1: LICENSE ACTION TYPE

THIS IS AN APPLICATION FOR (Check appropriate item)

Type of Action	License No.
❒ A. New License	Not Applicable
❒ B. Amendment to License No.	XX-XXXXX-XX
❒ C. Renewal of License No.	XX-XXXXX-XX

Check A if the application is for a new license.

Check B for an amendment[1] to an existing license, and provide license number.

Check C for a renewal[1] of an existing license, and provide license number.

8.2 ITEM 2: APPLICANT'S NAME AND MAILING ADDRESS

Regulations: 10 CFR 30.34(b); 10 CFR 35.14(b); 10 CFR 30.34(h).

List the legal name of the applicant's corporation or other legal entity with direct control over use of the radioactive material; a division or department within a legal entity may not be a licensee. An individual may be designated as the applicant only if the individual is acting in a private capacity and the use of the radioactive material is not connected with employment in a corporation or other legal entity. Provide the mailing address where correspondence should be sent. A post office box number is an acceptable mailing address.

Note: NRC must be notified before control of the license is transferred or whenever bankruptcy proceedings are initiated. See below for more details. NRC IN 97-30, "Control of Licensed Material during Reorganizations, Employee-Management Disagreements, and Financial Crises," dated June 3, 1997, discusses the potential for the security and control of licensed material to be compromised during periods of organizational instability.

[1] See "Amendments and Renewals to a License" in this document. Licensees may request an amendment to an existing license to add authorization for other uses of byproduct material.

Timely Notification of Transfer of Control

Regulations: 10 CFR 30.34(b); 10 CFR 35.14(b).

Criteria: Licensees must provide full information and obtain NRC's *written consent* before transferring control of the license, or, as some licensees refer to the process, "transferring the license."

Discussion: Control may be transferred as a result of mergers, buyouts, or majority stock transfers. Although it is not NRC's intent to interfere with the business decisions of licensees, it is necessary for licensees to obtain NRC written consent before transferring control of the license. This is to ensure the following:

- Radioactive materials are possessed, used, or controlled only by persons who have valid NRC licenses;
- Materials are properly handled and secured;
- Persons using these materials are competent and committed to implementing appropriate radiological controls;
- A clear chain of custody is established to identify who is responsible for final disposal of the material;
- Public health and safety are not compromised by the use of such materials.

As provided in 10 CFR 35.14(b), if the licensee's name or mailing address changes, and the name change does not constitute a transfer of control of the license as described in 10 CFR 30.34(b), a licensee must file a written notification with NRC no later than 30 days after the dates of the change(s). Otherwise, prior NRC written consent must be given prior to the transfer.

Response from Applicant: No response is required for an applicant for a new license. Appendix D, excerpted from Appendix F of NUREG-1556, Vol. 15, identifies the information to be provided about transferring control.

Reference: See the Notice of Availability on the inside front cover of this report to obtain copies of IN 97-30, "Control of Licensed Material during Reorganizations, Employee-Management Disagreements, and Financial Crises," dated June 3, 1997, and NUREG-1556, Vol. 15, "Program-Specific Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Material Licenses," dated November 2000. These documents can also be accessed at NRC's web site, <http://www.nrc.gov>, under "Reference Library," then "Information Notices" or "Technical Reports (NUREGS)."

Notification of Bankruptcy Proceedings

Regulation: 10 CFR 30.34(h).

Criteria: Immediately following filing of a voluntary or involuntary petition for bankruptcy for or against a licensee, the licensee must notify the appropriate NRC Regional Administrator, in writing, identifying the bankruptcy court in which the petition was filed and the date the of filing.

Discussion: Even though a licensee may have filed for bankruptcy, the licensee remains responsible for compliance with all regulatory requirements. NRC needs to know when licensees are in bankruptcy proceedings in order to determine whether all licensed material is accounted for and adequately controlled and whether there are any public health and safety concerns (e.g., contaminated facility). NRC shares the results of its determinations with other entities involved (e.g., trustees) so that health and safety issues can be resolved before bankruptcy actions are completed.

Response from Applicant: No response is required from an applicant at the time of application for a new license. Licensees must notify NRC immediately (i.e., within 24 hours) of the filing of a bankruptcy petition.

Reference: See the Notice of Availability on the inside front cover of this report to obtain copies of Policy and Guidance Directive PG 8-11, "NMSS Procedures for Reviewing Declarations of Bankruptcy," dated August 8, 1996, and Inspection Procedure (IP) 87103, "Inspection of Material Licensee Involved in an Incident or Bankruptcy Filing."

8.3 ITEM 3: ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Regulations: 10 CFR 30.33(a)(2); 10 CFR 35.18.

Pursuant to 10 CFR 30.33(a)(2) and as referenced in NRC Form 313 Item 3, specify the street address, city, and state or other descriptive address (e.g., on Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234, Anytown, State) for each facility. The descriptive address should be sufficient to allow an NRC inspector to find the facility location. A post office box address is not acceptable (see Figure 8.1). If byproduct material is to be used at more than one location under the license, the specific address (e.g., street and building) must be provided for each facility. Refer to P&GD PG 1-23, "Guidance for Multi-Site Licenses," for additional guidance on applying for use at multiple sites. If applying for a license for a mobile service as authorized pursuant to 10 CFR 35.18(b), the applicant should refer to Section 8.42 and Appendix V of this report for specific licensing guidance.

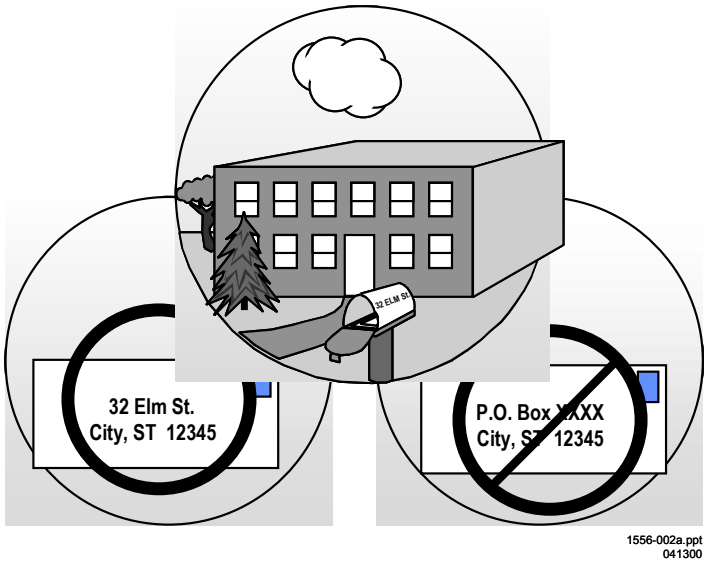

Figure 8.1 Location of Use.

Being granted an NRC license does not relieve a licensee from complying with other applicable Federal, State, or local regulations (e.g., local zoning requirements; a local ordinance requiring registration of a radiation-producing device).

Note: As discussed in "Financial Assurance and Recordkeeping for Decommissioning" below, licensees must maintain permanent records on where the licensed material was used or stored while the license was in effect. These records are important for making future determinations about the release of these locations for unrestricted use (e.g., before the license is terminated). For medical use licensees, acceptable records include sketches and written descriptions of the specific locations where material is (or was) used or stored and any information relevant to spills (e.g., where contamination remains after cleanup procedures or when there is reasonable likelihood that contaminants may have spread), damaged devices, or leaking radioactive sources.

8.4 ITEM 4: PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Identify the individual who can answer questions about the application and include his or her telephone number. This is typically the proposed RSO, unless the applicant has named a different person as the contact. NRC will contact this individual if there are questions about the application.

Notify NRC if the contact person or his or her telephone number changes, so that NRC can contact the applicant or licensee in the future with questions, concerns, or information. This notice is for "information only" and does not require a license amendment or a fee.

The individual named in Item 4 may or may not be the same individual who signs the application as the "certifying officer" on behalf of the licensee with the authority to make commitments to NRC (see Item 13 on NRC Form 313). Any commitments the applicant makes should be signed by the individual named in Item 13 since only that individual is considered by NRC to have the authority to make commitments on behalf of the applicant. Therefore, NRC will not accept license amendments or renewals signed by the individual identified in Item 4 if this person differs from the one named in Item 13.

NRC recognizes that licensees may use a consultant or consultant group to help prepare the license application and provide support to the radiation protection program. However, NRC reminds licensees that regardless of the role of the consultant in radiation protection program management, the licensee remains responsible for all aspects of the licensed program, including the services performed by the consultant.

8.5 ITEM 5: RADIOACTIVE MATERIAL

Regulations: 10 CFR 30.32; 10 CFR 30.33; 10 CFR 30.34; 10 CFR 30.35; 10 CFR 32.210; 10 CFR 35.12; 10 CFR 35.65; 10 CFR 35.100; 10 CFR 35.200; 10 CFR 35.300; 10 CFR 35.400; 10 CFR 35.500; 10 CFR 35.600; 10 CFR 35.1000.

Criteria: 10 CFR Part 35 divides byproduct material for medical use into seven types of use (10 CFR 35.100, 35.200, 35.300, 35.400, 35.500, 35.600, and 35.1000).

Discussion: Using the table formats below (see Table 8.1), the applicant should indicate the byproduct material requested. For 35.100, 35.200, and 35.300 material, the chemical/physical form may be "Any." In accordance with Item 5 on NRC Form 313, the maximum amount that will be possessed at any one time must be specified. For 35.100 and 35.200 material, the total amount requested may be "As Needed." For 35.300 material, the total amount requested must be specified. For 35.400, 35.500, 35.600, and 35.1000 material, the radionuclide, the chemical/physical form (e.g., sealed source and manufacturer's name and model number), the total amount in Becquerels (Bq), microcuries (μCi), millicuries (mCi), or curies (Ci), and maximum number of sources or activity possessed at any one time must be specified. For calibration, transmission, and reference sources covered under 10 CFR 35.65, the specific sources do not need to be listed on the license as long as the licensee is authorized pursuant to 10 CFR 35.11 for medical use of byproduct material.

For sealed sources used in devices, an applicant may wish to request two sources, one to be used in the device and one to be stored in its shipping container, to accommodate the total quantity of material in the licensee's possession during replacement of the source in the device. Pursuant to 10 CFR 30.32 and 10 CFR 32.210, the maximum activity for a single source or source loading may not exceed the activity specified by the manufacturer for the specific device and source combination as stated in the Sealed Source and Device Registration (SSDR) Certificate. However, it is permissible to request a maximum activity for the source in the shipping container, that exceeds the maximum activity allowed in the device. To request this authorization, applicants should provide certification that the source transport container is approved for the requested activity. A source that is received with a higher activity than permitted in the device must be allowed to decay to or below the device source activity limit prior to installation in the device.

If applicable, the applicant should request authorization to possess depleted uranium (i.e., uranium depleted in uranium-235 (U-235)) in quantities sufficient to include shielding material in both the device(s) and source containers used for source exchange. The applicant should review the manufacturer's specifications for each device specified in the license request to determine: (1) if depleted uranium is used to shield the source(s) within the device; and (2) the total quantity of depleted uranium present in the device (in kilograms). The applicant should also consult the manufacturer's specifications or the source supplier to determine if depleted uranium is contained in shielding source containers used during source exchange, as well as the total quantity of depleted uranium in such containers (in kilograms).

The applicant should make a separate entry for other items that need to be listed (e.g., more byproduct material for *in vitro* testing than is allowed under 10 CFR 31.11, depleted uranium for linear accelerator shielding, survey meter calibration source, dosimetry system constancy check source, material for *in vitro*, animal, or human research studies). Sources that are authorized by 10 CFR 35.65, "Authorization for calibration, transmission, and references sources," should *not* be listed. Applicants should number each line entry consecutively, following the 10 CFR Part 35 material.

Table 8.1 Sample Format for Byproduct Material.

Byproduct Material	Chemical/Physical Form	Maximum Amount
Any byproduct material included in 10 CFR 35.100	Any	As needed
Any byproduct material included in 10 CFR 35.200	Any	As needed
Any byproduct material included in 10 CFR 35.300	Any	300 millicuries
Cesium 137 (i.e., specific brachytherapy radionuclide)	Sealed source (Manufacturer Name, Model #XYZ)	2 curies total
Gadolinium 153 (i.e., specific diagnostic sealed source radionuclide)	Sealed source (Manufacturer Name, Model #XYZ)	Not to exceed 500 millicuries per source and 1 curie total
Cobalt 60 (i.e., specific teletherapy sealed source radionuclide)	Sealed source (Manufacturer Name, Model #XYZ)	Not to exceed 9,000 curies per source and 18,000 curies total
Iridium 192 (i.e., specific afterloader sealed source radionuclide)	Sealed source (Manufacturer Name, Model #XYZ)	Not to exceed 10 curies per source and 20 curies total
Cobalt 60 (i.e., specific gamma stereotactic radiosurgery sealed source radionuclide)	Sealed source (Manufacturer Name, Model #XYZ)	Not to exceed 36 curies per source and 6,600 curies total
Depleted Uranium	Metal	99 kilograms
Any byproduct material identified in 10 CFR 31.11	Prepackaged kits	50 millicuries

When determining both individual radionuclide and total quantities, all materials to be possessed at any one time under the license should be included [i.e., materials received awaiting use (new teletherapy or brachytherapy sources for exchange), materials in use or possessed, material used for shielding, and materials classified as waste awaiting disposal or held for “decay-in-storage (DIS)”].

Response from Applicant: The applicant shall submit the information as described above.

8.6 ITEM 5: FINANCIAL ASSURANCE AND RECORDKEEPING FOR DECOMMISSIONING

Regulations: 10 CFR 30.34(b); 10 CFR 30.35.

Criteria: Licensees authorized to possess licensed material in excess of the limits specified in 10 CFR 30.35 must provide evidence of financial assurance for decommissioning.

Even if no financial assurance is required, licensees are required, under 10 CFR 30.35(g), to maintain records important to decommissioning in an identified location (see Figure 8.2). These records must, in part, identify all areas where licensed material is (or was) used or stored and any information relevant to spills (e.g., where contamination remains after cleanup procedures or when there is a reasonable likelihood that contaminants may have spread) and leaking sealed sources. As an alternative to the potential need for site characterizations, some licensees prefer to maintain information on surveys and leak tests on an ongoing basis and as a low-cost means of providing evidence and assurance of an appropriate decommissioning status upon the termination of licensed activities and/or release of a site for non-licensed use. Licensees must transfer the records important to decommissioning either to the new licensee before licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b), or to the appropriate NRC Regional Office before the license is terminated.

Figure 8.2 Decommissioning Records.

Discussion: The requirements for financial assurance are specific to the types and quantities of byproduct material authorized on a license. Most medical use applicants and licensees do not need to take any action to comply with the financial assurance requirements because either their total inventory of licensed material does not exceed the limits in 10 CFR 30.35 or because the half-life of the unsealed byproduct material used does not exceed 120 days. Applicants

requesting licensed material with a half-life in excess of 120 days should determine whether financial assurance is necessary. In addition, applicants requesting more than one radionuclide must use the sum-of-the-ratios method to determine if financial assurance is needed. See Appendix E for additional information.

Applicants and licensees that want to possess licensed materials exceeding the limits in 10 CFR 30.35 must submit evidence of financial assurance or a decommissioning funding plan (10 CFR 30.35 (b)). Figure 8.3 depicts acceptable methods of providing financial assurance. Regulatory Guide (RG) 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72," dated June 1990, contains approved wording for each mechanism authorized by the regulation to guarantee or secure funds, except for the Statement of Intent for Government licensees. See Appendix E for the recommended wording for a Statement of Intent.

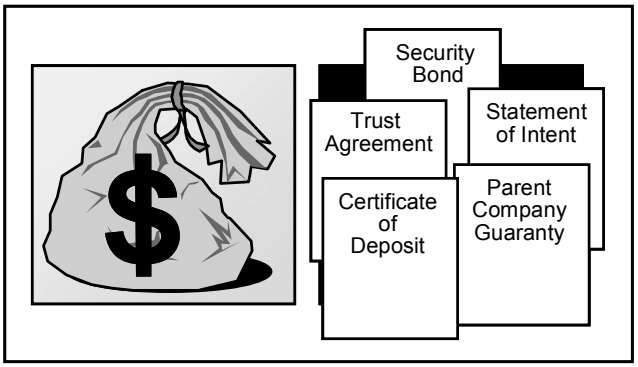

Figure 8.3 Financial Assurance Mechanisms.

NRC will authorize sealed source possession exceeding the limits given in 10 CFR 30.35(d) without requiring decommissioning financial assurance, for the purpose of normal sealed source exchange, for no more than 30 days. Table 8.2 shows examples of the limits for select sealed sources.

Table 8.2 Minimum Sealed Source Inventory Quantity Requiring Financial Assurance.

Radionuclide	Activity in GBq	Activity in Ci
cesium-137 (Cs-137)	3.7×10^6	100,000
cobalt-60 (Co-60)	3.7×10^5	10,000
strontium-90 (Sr-90)	3.7×10^4	1,000

Licensees using sealed sources authorized by 10 CFR 35 generally use licensed material in a manner that would preclude releases into the environment, would not cause the activation of adjacent materials, or would not contaminate work areas. The licensee's most recent leak test should demonstrate that there has been no leakage from the sealed sources while the sealed sources were in the licensee's possession. However, any leakage of the sealed source in excess of the regulatory limits would warrant further NRC review of decommissioning procedures on a case-by-case basis.

Response from Applicants: No response is needed from most applicants. If financial assurance is required, applicants must submit evidence as described in RG 3.66.

Pursuant to 10 CFR 30.35(g), licensees must transfer records important to decommissioning either to the new licensee before licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b) or to the appropriate NRC Regional Office before the license is terminated.

Reference: See the Notice of Availability on the inside front cover of this report to obtain copies of Regulatory Guide 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72," dated June 1990, and Policy and Guidance Directive FC 90-2 (Rev. 1), "Standard Review Plan for Evaluating Compliance with Decommissioning Requirements," dated April 30, 1991.

8.7 ITEM 5: SEALED SOURCES AND DEVICES

Regulations: 10 CFR 30.32(g); 10 CFR 30.33(a)(2); 10 CFR 32.210.

Criteria: In accordance with 10 CFR 30.32(g), applicants must provide the manufacturer's name and model number for each requested sealed source and device (except for calibration, transmission, and reference sources authorized by 10 CFR 35.65). Licensees will be authorized to possess and use only those sealed sources and devices specifically approved or registered by NRC or an Agreement State.

Discussion: NRC or an Agreement State performs a safety evaluation of sealed sources and devices before authorizing a manufacturer to distribute the sources or devices to specific licensees. The safety evaluation is documented in an SSDR Certificate. Applicants must provide the manufacturer's name and model number for each requested sealed source and device so that NRC can verify that they have been evaluated in an SSDR Certificate or specifically approved on a license. If such a review has not been conducted for the specific source/device model(s), licensees should request a copy of NUREG-1556, Vol. 3, "Consolidated Guidance about Materials Licensees: Applications for Sealed Source and Device Evaluation and Registration,"

dated July 1998, from the NRC Regional Office and submit the information requested therein to NRC for review.

An applicant may consult with the proposed supplier or manufacturer to ensure that requested sources and devices are compatible with each other and that they conform to the SSDR designations registered with NRC or an Agreement State. Licensees may not make any changes to the sealed source, device, or source-device combination that would alter the description or specifications from those indicated in the respective SSDR Certificates without obtaining NRC's prior permission in a license amendment. To ensure that sealed sources and devices are used in ways that comply with the registration certificates, applicants may want to obtain copies of the certificates and review or discuss them with the manufacturer. A compilation of these registration certificates may be found at <http://www.hsrd.ornl.gov/nrc/ssdr/ssdrindx.html>.

In addition, many sealed sources must have a National Institute of Standards and Technology (NIST) traceable calibration prior to use. Refer to Section 8.41 for additional information on calibration of therapy sealed sources.

Response from Applicant: If possession of sealed source(s) or device(s) is requested, the applicant shall submit the information described above.

Reference: See the Notice of Availability on the inside front cover of this report to obtain a copy of NUREG-1556, Vol. 3, "Consolidated Guidance about Materials Licensees: Applications for Sealed Source and Device Evaluation and Registration," dated July 1998.

Note: Information on SSD registration certificates is also available on the Internet at <http://www.hsrd.ornl.gov/nrc/ssdr/ssdrindx.html> or by calling the NRC Registration Assistant toll-free at (800) 368-5642, extension 415-7217.

8.8 ITEM 6: PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

Regulations: 10 CFR 30.32(b); 10 CFR 30.33(a)(1); 10 CFR 35.100; 10 CFR 35.200; 10 CFR 35.300; 10 CFR 35.400; 10 CFR 35.500; 10 CFR 35.600; 10 CFR 35.1000.

Criteria: 10 CFR Part 35 divides byproduct material for medical use into seven types of use as follows:

10 CFR 35.100	Medical Use of Unsealed Byproduct Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive is Not Required
10 CFR 35.200	Medical Use of Unsealed Byproduct Material for Imaging and Localization Studies for Which a Written Directive is Not Required
10 CFR 35.300	Medical Use of Unsealed Byproduct Material for Which a Written Directive is Required
10 CFR 35.400	Medical Use of Sources for Manual Brachytherapy
10 CFR 35.500	Medical Use of Sealed Sources for Diagnosis
10 CFR 35.600	Medical Use of a Sealed Source(s) in a Device for Therapy-Teletherapy Unit
10 CFR 35.600	Medical Use of a Sealed Source(s) in a Device for Therapy-Remote Afterloader Unit
10 CFR 35.600	Medical Use of a Sealed Source(s) in a Device for Therapy-Gamma Stereotactic Radiosurgery Unit
10 CFR 35.1000	Other Medical Uses of Byproduct Material or Radiation from Byproduct Material (Emerging Technology)

Discussion: For 35.100, 35.200, and 35.300 material, the applicant should define the purpose of use by stating the applicable section of 10 CFR Part 35 (e.g., 10 CFR 35.100, 10 CFR 35.200) and the description of the applicable modality (e.g., any uptake dilution and excretion procedure approved in 10 CFR 35.100).

The use of unsealed byproduct material in therapy (10 CFR 35.300) involves administering a radiopharmaceutical, either orally or by injection, to treat or palliate a particular disease. The most common form of radiopharmaceutical therapy is the treatment of hyperthyroidism with iodine-131 (I-131) sodium iodide. Other therapeutic procedures include ablation of thyroid cancer metastases, treatment of malignant effusions, treatment of polycythemia vera and leukemias, palliation of bone pain in cancer patients, and radiation synovectomy for rheumatoid arthritis patients. Table 8.3 contains a summary of several therapeutic radiopharmaceuticals and their uses.

If only requesting a specific radioisotope for therapy use under 10 CFR 35.300, the applicant should provide the information as described in the table below.

Table 8.3 Radiopharmaceuticals Used in Therapy.

Agent	Form	Route of Administration	Therapeutic Use
I-131 sodium iodide	solution/ capsules	oral	hyperthyroidism thyroid carcinoma total body scan for thyroid metastases (diagnostic)
phosphorus-32 (P-32) chromic phosphate	colloidal suspension	intraperitoneal or intrapleural cavity injection	peritoneal or pleural effusions
P-32 sodium phosphate	solution	oral or IV	polycythemia vera leukemias
strontium-89 chloride	solution	IV	skeletal metastases
samarium-153 EDTMP	solution	IV	skeletal metastases
rhenium-186 HEDP	solution	IV	skeletal metastases
tin-117m DTPA	solution	IV	skeletal metastases
dysprosium-165 FHMA	aggregate in solution	IV	rheumatoid arthritis
yttrium-90 FHMA	aggregate in solution	IV	rheumatoid arthritis

For 35.400 material, the applicant should define the purpose of use by stating the applicable section of 10 CFR Part 35 (i.e., 10 CFR 35.400). If a source is to be used in a device, applicants may need to define the purpose of use by describing the manufacturer's name and model number of the device. The licensee should correlate the sealed sources listed in Item 5 with the devices described in this item.

In manual brachytherapy several types of treatments are available. These may include:

- Interstitial Treatment of Cancer. The following sources are routinely used:
  - — Cs-137 and Co-60 as a sealed source in needles and applicator cells;
  - — iridium-192 (Ir-192) as seeds encased in nylon ribbon;
  - — gold-198, iodine-125 (I-125), and palladium-103 (Pd-103) as a sealed source in seeds.
- Eye Plaque Implants. The eye plaque consists of a curved soft plastic insert that has a series of grooves molded into the rear convex surface that are designed to hold radioactive seeds. After the plastic insert is loaded with the seeds, a solid gold cover, matched in size to the insert, is placed over the convex surface of the insert and cemented in place to seal the seeds into a fixed array within the plaque. The insert is completely surrounded by the gold cover except for the concave surface that is placed against the eye. When used with I-125 and Pd-103 seeds, the gold cover provides considerable shielding of the normal tissues surrounding the eye and limits the external dose rates surrounding the patient. Although not implanted into the tumor, because the plaque is placed in the orbit of the eye over the tumor site and sutured to the sclera of the eye to stabilize its position on the tumor while in the orbit, this is considered interstitial, not topical, treatment.
- Intracavitary Treatment of Cancer. For purposes of NRC's sealed source and device evaluation on radiation safety issues, intraluminal use is considered analogous to intracavitary use. The following sources are routinely used for the intracavitary treatment of cancer:
  - — Cs-137 and Co-60 as a sealed source in needles and applicator cells;
  - — Ir-192 and Pd-103 seeds.
- Topical (Surface) Applications. The following sources are routinely used for topical applications:
  - — Cs-137 and Co-60 as sealed sources in needles and applicator cells;
  - — Sr-90 as a sealed source in an applicator for treatment of superficial eye conditions.

For 10 CFR 35.500 material, the applicant should define the purpose of use by stating the applicable section of 10 CFR 35 (i.e., 10 CFR 35.500) and describing the manufacturer's name(s) and model number(s) of devices containing sealed sources (where applicable). The licensee should correlate the sealed sources listed in Item 5 with the devices described in this item. Typically, a licensee should use the following sealed sources according to manufacturer's radiation safety and handling instructions and must use the sources as approved in the SSDR:

- I-125, americium-241, or gadolinium-153 as a sealed source in a device for bone mineral analysis;
- I-125 as a sealed source in a portable imaging device.

For 10 CFR 35.600 material, the applicant should define the purpose of use by stating the applicable section of 10 CFR Part 35.600 (e.g., teletherapy, remote afterloading, GSR) and describing the manufacturer's name(s) and model number(s) of the device containing a sealed source(s) (e.g., for use in a Manufacturer's Name and Unit Type, Model xxxx radiation therapy unit for the treatment of humans). Figure 8.4 shows a schematic of a GSR unit. The applicant should correlate the sealed source(s) listed in Item 5 with the device described in this item. If applicable, the applicant should state that depleted uranium is used as shielding for the device and specify that an additional source is requested to be stored in its shipping container incident to source replacement.

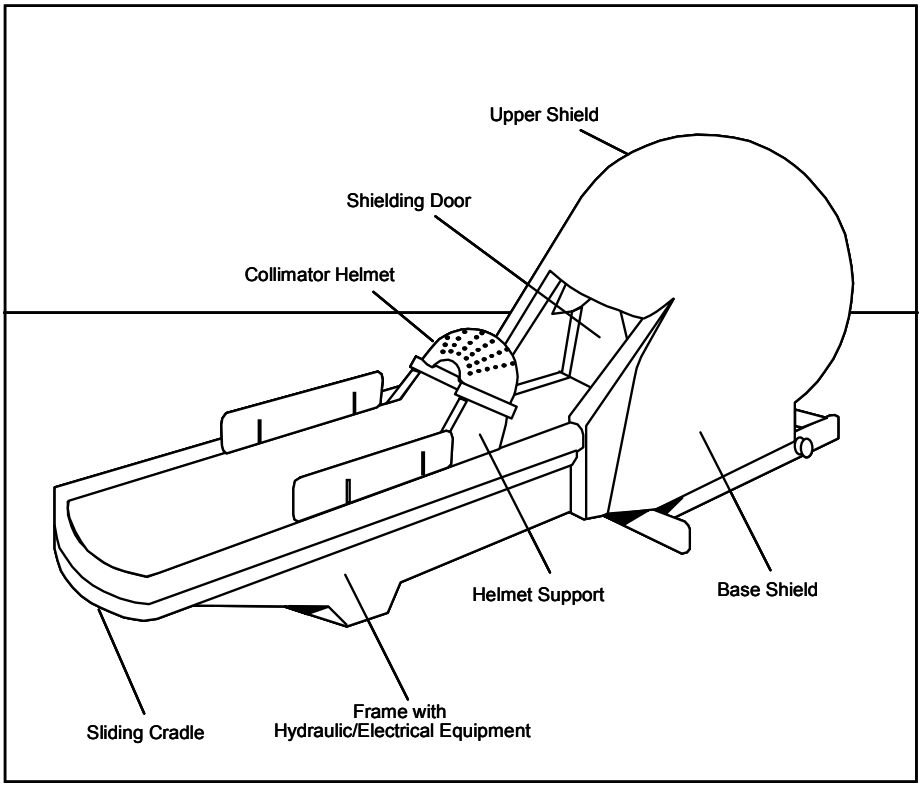

Figure 8.4 Gamma Stereotactic Radiosurgery Unit.

For 10 CFR 35.1000 material, the applicant should define the purpose of use and list the manufacturer's name(s) and model number(s) of the device containing a sealed source(s) (where applicable). The licensee should correlate the sealed sources listed in Item 5 with the devices described in this item.

An example of an "emerging technology" (byproduct material approved for medical use not specifically addressed elsewhere in 10 CFR Part 35) is the use of byproduct material to prevent restenosis following angioplasty. Some research institutions have shown that post-operative radiation exposure reduces the probability of such restenosis. Radionuclides that are used in emerging technologies for restenosis include P-32, Sr-90, Ir-192, rhenium-186, rhenium-188, xenon-133, and hydrogen-3.

Emerging technologies for restenosis have been developed using radioactive catheters, pellets, and stents to treat coronary and peripheral vascular problems. These therapy devices contain ionizing radiation in the form of a gas, liquid, or solid that retards recoil and proliferation of smooth muscle cells in the affected vessel wall. The radiation can be ion implanted, plated, or encapsulated in a sealed source device attached to a guide wire used in the angioplasty procedure. The radioactive device can be permanently implanted, or it can be removed with the guide wire following treatment of the affected vessel wall.

Intracoronary radiation therapy is emerging as the primary discipline of the new technology. Several innovative types of intravascular radiation therapy devices for use after balloon angioplasty are being clinically investigated and include:

- Intracoronary Beta and/or Photon Radiation Catheter (Figure 8.5) – The catheter is not an implant and the radiation is delivered after a balloon angioplasty.
- Intracoronary Beta and/or Photon Radiation Stent (Figure 8.6) – The stent is a permanent implant and the radiation is delivered after balloon angioplasty.
- Intracoronary Beta and/or Photon Radiation Pellets – The pellets are a temporary implant and the radiation is delivered after balloon angioplasty.

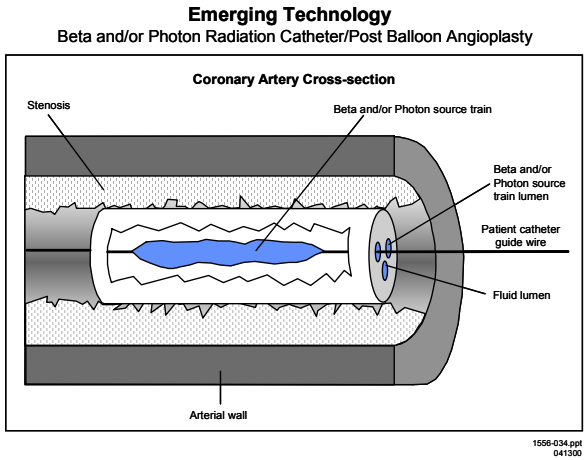

Figure 8.5 Beta and/or Photon Radiation Catheter.

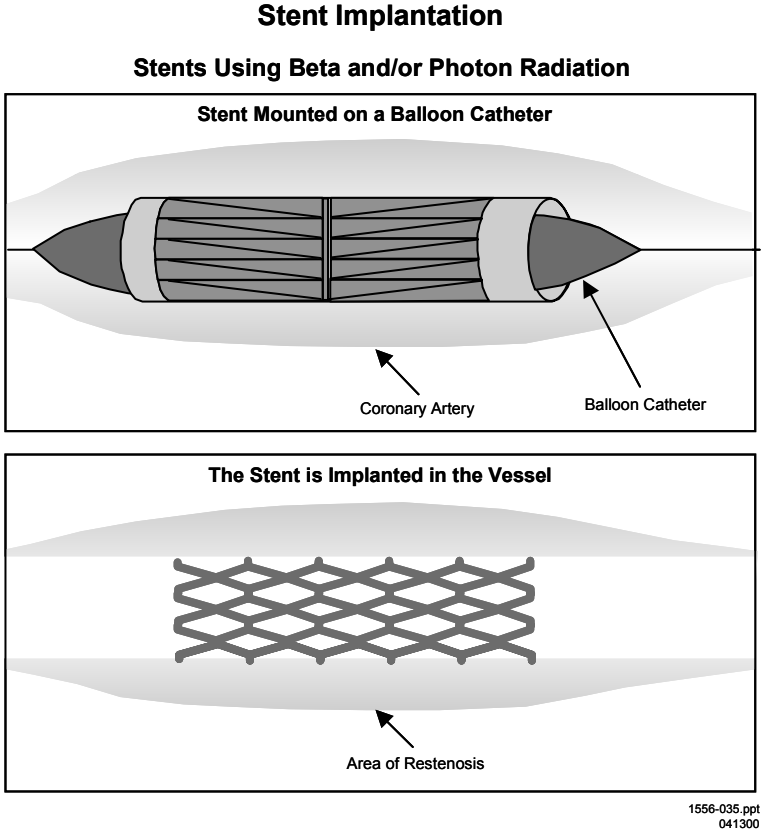

Figure 8.6 Stent Implantation.

The United States Food and Drug Administration (FDA) has considered the use of radiation in the coronary and/or peripheral vasculature for the prevention of restenosis investigational with the potential for risk to patients. Legal and ethical considerations require U.S. patients be studied under an FDA "investigational device exemption" application. An "investigational device exemption" from the FDA does not preclude the necessity for an NRC license for the byproduct material. At the time of this writing, a couple of devices have been approved by the FDA for routine clinical use under the conditions of use as specified by the FDA. If the source is a sealed source, Section 8.7 describes the type of sealed source and device information that must be provided at the time of application. Additionally, broad scope licensees should refer to IN 99-024, "Broad-Scope Licensees' Responsibilities for Reviewing and Approving Unregistered Sealed Sources and Devices."

Applicants may also describe non-medical uses (e.g., survey meter calibrations with NIST traceable brachytherapy sources) and reference the applicable radioactive material provided in response to Item 5.

Appendix C contains sample licenses that provide guidance on how to respond to Item 6.

Response from Applicant: The applicant shall submit the information described above.

8.9 ITEM 7: INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE

Regulations: 10 CFR 30.33(a)(3); 10 CFR 35.24; 10 CFR 35.50; 10 CFR 35.51; 10 CFR 35.55; 10 CFR 35.57; 10 CFR 35.59; 10 CFR 35.190; 10 CFR 35.290; 10 CFR 35.390; 10 CFR 35.392; 10 CFR 35.394; 10 CFR 35.490; 10 CFR 35.491; 10 CFR 35.590; and 10 CFR 35.690.

Criteria: The RSO, AUs, AMPs, and ANPs must have adequate training and experience.

Discussion: 10 CFR 35.24 provides the requirements regarding the authority and responsibilities for the radiation protection program, including those of the licensee's management and the RSO appointed by licensee management. Other personnel who have a role in the radiation protection program are AUs, members of the RSC (if required to establish), AMPs, and ANPs. In 10 CFR 30.33(a)(3), NRC requires that an applicant be qualified by training and experience to use licensed materials for the purposes requested in such a manner as to protect health and minimize danger to life or property. Subparts B, D, E, F, G, and H of 10 CFR Part 35 give specific criteria for acceptable training and experience for AUs for medical use, ANPs, the RSO, and AMPs.

Applicants should note that a résumé or a curriculum vitae does not usually supply all the information needed to evaluate an individual's training and experience for NRC purposes because these documents often list publications rather than specific training required by NRC regulations.

NRC holds the licensee responsible for the radiation protection program. Therefore, it is essential that strong management control and oversight exist to ensure that licensed activities are conducted properly. The licensee's management must appoint an RSO, who agrees in writing to be responsible for implementing the radiation protection program, and must provide the RSO sufficient authority, organizational freedom, time, resources, and management prerogative to communicate with personnel and direct personnel regarding NRC regulations and license provisions, including: identifying radiation safety problems; initiating, recommending, or providing corrective actions; stopping unsafe operations; and verifying the implementation of corrective actions. Nevertheless, the licensee retains the ultimate responsibility for the conduct of licensed activities. In addition, licensees that are authorized for two or more different types of uses of byproduct material under Subparts E, F, and H, or two or more types of units under Subpart H, must establish an RSC to oversee all uses of byproduct material permitted by the license.

Licensees may contract for medical use services, including those involving patient services. However, the licensee should not assume that by hiring a contractor to provide certain services it has satisfied all regulatory requirements or that it has transferred responsibility for the licensed program to the contractor. Licensee management should ensure that adequate mechanisms for oversight are in place to determine that the radiation protection program is effectively implemented by the appropriate individuals.

Response from Applicant: Refer to the subsequent sections specific to the individuals described above.

8.10 ITEM 7: RADIATION SAFETY OFFICER (RSO)

Regulations: 10 CFR 30.33(a)(3); 10 CFR 35.14; 10 CFR 35.24; 10 CFR 35.50; 10 CFR 35.57; 10 CFR 35.59; 10 CFR 35.2024.

Criteria: RSOs must have adequate training and experience. The training and experience requirements for the RSO are described in 10 CFR 35.50[2] and allow for the following three training pathways:

- Certification by one of the professional boards recognized by NRC;
- Didactic and work experience as described in item b of 10 CFR 35.50[2];
- Identification on the license as an AU, AMP, or ANP with experience in the radiation safety aspects of similar types of byproduct material use for which the individual has RSO responsibilities[2].

The licensee must also establish, in writing, the authority, duties, and responsibilities of the RSO.

Discussion: The RSO is responsible for day-to-day oversight of the radiation protection program. In accordance with 10 CFR 35.24, the licensee must provide the RSO sufficient authority, organizational freedom, time, and resources to perform his or her duties. Additionally, the RSO must have a sufficient commitment from management to fulfill the duties and responsibilities specified in 10 CFR 35.24 to ensure that radioactive materials are used in a safe manner. NRC requires the name of the RSO on the license, and an agreement in writing from the RSO, to ensure that licensee management has identified a responsible, qualified person and that the named individual knows of his or her designation and assumes the responsibilities of an RSO. Usually, the RSO is a full-time employee of the licensed facility; however, NRC has authorized individuals that are not employed by the licensee, such as a consultant, to fill the role of RSO or to provide support to the facility RSO. However, the RSO must be physically present at the facility for a specified amount of time, commensurate with the licensed activities of the facility, during normal working hours to provide the opportunity for interaction with the licensee's staff involved with licensed material. Typical RSO duties are illustrated in Figure 8.7 and described in Appendix F. Appendix F also contains a model RSO Delegation of Authority. Appendix G contains forms that can be used to document the RSO's training and experience.

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[2] The requirement to meet the training and experience requirements in 10 CFR 35.50, including the limitation that an AU can be named the RSO only for the types of use for which the individual has training and experience, will become effective 6 months after the publication of the final rule (10 CFR Part 35).

[2] The requirement to meet the training and experience requirements in 10 CFR 35.50, including the limitation that an AU can be named the RSO only for the types of use for which the individual has training and experience, will become effective 6 months after the publication of the final rule (10 CFR Part 35).

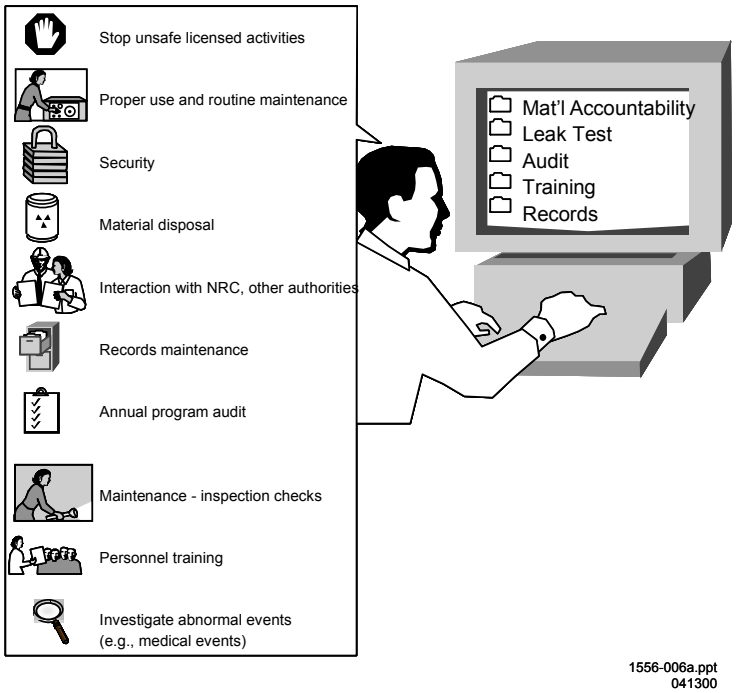

Figure 8.7 RSO Responsibilities. *Typical duties and responsibilities of RSOs.*

Applicants are reminded of recentness of training requirements described in 10 CFR 35.59. Specifically, RSO applicants must have successfully completed the applicable training and experience criteria described in 10 CFR Part 35 within 7 years preceding the date of the application. Alternatively, RSO applicants must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other recognized training pathways.

Response from Applicant: Provide the following:

- Name of the proposed RSO.

AND

- Delegation of Authority and the written agreement of the RSO to be responsible for implementing the radiation protection program (see Appendix F).

AND

- Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) that authorized the uses requested and on which the individual was specifically named as the RSO.

OR

- Copy of the certification(s) for the board(s) recognized by NRC and as applicable to the types of use for which he or she has RSO responsibilities.

OR

- Description of the training and experience demonstrating that the proposed RSO is qualified by training and experience as applicable to the types of use for which he or she has RSO responsibilities. NRC Forms 313A and 313B may be used for this purpose (see Appendix G).

AND

- Written certification, signed by a preceptor RSO, that the above training and experience has been satisfactorily completed and that a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use licensee has been achieved.

Notes:

- The licensee must notify NRC within 30 days if an RSO permanently discontinues his or her duties under the license or has a name change under 10 CFR 35.14 and to request an amendment to change an RSO under 10 CFR 35.13.
- An AU, AMP, or ANP may be designated as the RSO on the license if the individual has training and experience with the radiation safety aspects of similar types of byproduct material use for which he or she has RSO responsibilities and, as required by 10 CFR 35.24(g), has sufficient time, authority, organizational freedom, resources, and management prerogative to perform the duties.
- Descriptions of training and experience will be reviewed using the criteria listed above. NRC will review the documentation to determine if the applicable criteria in Subpart B are met. If the training and experience do not appear to meet the Subpart B criteria, NRC may request additional information from the applicant or may request the assistance of its Advisory Committee on the Medical Uses of Isotopes (ACMUI) in evaluating such training and experience. Referrals to the ACMUI are normally limited to new types of medical use not previously described in the regulations or guidance.

8.11 ITEM 7: AUTHORIZED USERS

Regulations: 10 CFR 30.33(a)(3); 10 CFR 35.11; 10 CFR 35.14; 10 CFR 35.27; 10 CFR 35.57; 10 CFR 35.59; 10 CFR 35.190; 10 CFR 35.290; 10 CFR 35.390; 10 CFR 35.392; 10 CFR 35.394; 10 CFR 35.490; 10 CFR 35.491; 10 CFR 35.590; 10 CFR 35.690.

Criteria: AUs must have adequate training and experience. The training and experience requirements for physician-AUs are described in 10 CFR 35.190, 10 CFR 35.290, 10 CFR 35.390, 10 CFR 35.392, 10 CFR 35.394, 10 CFR 35.490, 10 CFR 35.491, 10 CFR 35.590, or 10 CFR 35.690.

Discussion: An AU is defined in 10 CFR 35.2, "Definitions." Included in the responsibilities of AUs involved in medical use are the following:

- Radiation safety commensurate with use of byproduct material;
- Administration of a radiation dose or dosage and how it is prescribed;
- Direction of individuals under the AU's supervision in the medical use of byproduct material;
- Preparation of WDs, if required.

Technologists, therapists, or other personnel may use byproduct material for medical use under an AU's supervision in accordance with 10 CFR 35.27, "Supervision," and in compliance with applicable FDA, other Federal, and State requirements (10 CFR 35.7).

For *in vitro* studies, calibration of survey instruments, and other uses that do not involve the intentional exposure of humans, the list of proposed AUs should include the individuals who will actually be responsible for the safe use of the byproduct material for the requested use. An applicant should note which user will be involved with a particular use by referring to Items 5 and 6 of the application and providing the user's training and experience.

Applicants are reminded of recentness of training requirements described in 10 CFR 35.59. Specifically, physician-AU applicants must have successfully completed the applicable training and experience criteria described in 10 CFR Part 35 within 7 years preceding the date of the application. Alternatively, physician-AU applicants must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other recognized training pathways.

Response from Applicant: Provide the following:

- Name of the proposed AU and uses requested.

AND

- Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) on which the physician was specifically named as an AU for the uses requested.

OR

- Copy of the certification(s) for the board(s) recognized by NRC and as applicable to the use requested.

OR

- Description of the training and experience demonstrating that the proposed AU is qualified by training and experience for the use requested. NRC Forms 313A and 313B may be used for this purpose (see Appendix G).

AND

- Written certification, signed by a preceptor physician AU, that the above training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an AU for the medical uses authorized has been achieved.

Notes:

- Licensees must notify NRC within 30 days if an AU permanently discontinues his or her duties under the license or has a name change under 10 CFR 35.14.
- Descriptions of training and experience will be reviewed using the criteria listed above. NRC will review the documentation to determine if the applicable criteria in 10 CFR Part 35 are met. If the training and experience do not appear to meet the 10 CFR Part 35 criteria, NRC may request additional information from the applicant or may request the assistance of its ACMUI in evaluating such training and experience. Referrals to the ACMUI are normally limited to new types of medical use not previously described in the regulations or guidance.
- Authorized non-medical use or uses that do not involve the intentional exposure of humans (e.g., *in vitro* and animal research, calibration, dosimetry research) will be reviewed on a case-by-case basis.

8.12 ITEM 7: AUTHORIZED NUCLEAR PHARMACIST

Regulations: 10 CFR 30.33(a)(3); 10 CFR 35.11; 10 CFR 35.14; 10 CFR 35.27; 10 CFR 35.55; 10 CFR 35.57; 10 CFR 35.59.

Criteria: ANPs must have adequate training and experience. The training and experience requirements for ANPs are described in 10 CFR 35.55.

Discussion: An ANP is defined in 10 CFR 35.2, "Definitions." At many licensed medical facilities, an ANP is directly involved with the preparation and administration of radiopharmaceuticals.

Technologists, or other personnel, may prepare byproduct material for medical use under an ANP's supervision in accordance with 10 CFR 35.27, "Supervision," and in compliance with applicable FDA, other Federal, and State requirements (10 CFR 35.7).

Applicants are reminded of recentness of training requirements described in 10 CFR 35.59. Specifically, nuclear pharmacist applicants must have successfully completed the applicable training and experience criteria described in 10 CFR Part 35 within 7 years preceding the date of the application. Alternatively, nuclear pharmacist applicants must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other recognized training pathways.

Response from Applicant: Provide the following:

- Name of the proposed ANP.

AND

- Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) on which the individual was specifically named ANP.

OR

- Copy of the certification(s) for the radiopharmacy board(s) recognized by NRC.

OR

- Description of the training and experience demonstrating that the proposed ANP is qualified by training and experience. NRC Forms 313A and 313B may be used for this purpose (see Appendix G).

AND

- Written certification, signed by a preceptor ANP, that the above training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an ANP has been achieved.

Notes:

- Licensees must notify NRC within 30 days if an ANP permanently discontinues his or her duties under the license or has a name change under 10 CFR 35.14.
- Descriptions of training and experience will be reviewed using the criteria listed above. NRC will review the documentation to determine if the applicable criteria in Subpart B are met. If the training and experience do not appear to meet the Subpart B criteria, NRC may request additional information from the applicant or may request the assistance of its ACMUI in

evaluating such training and experience. Referrals to the ACMUI are normally limited to new types of medical use not previously described in the regulations or guidance.

8.13 ITEM 7: AUTHORIZED MEDICAL PHYSICIST

Regulations: 10 CFR 30.33(a)(3); 10 CFR 35.14; 10 CFR 35.51; 10 CFR 35.57; 10 CFR 35.59.

Criteria: AMPs must have adequate training and experience. The training and experience requirements for AMPs are described in 10 CFR 35.51.

Discussion: An AMP is defined in 10 CFR 35.2, "Definitions." At many licensed medical facilities conducting radiation therapy treatments, an AMP is directly involved with the calculation and administration of the radiation dose. The American Association of Physicists in Medicine (AAPM) suggests that a medical physicist limit his or her involvement in radiation therapy to areas for which he or she has established competency.

Applicants are reminded of recentness of training requirements described in 10 CFR 35.59. Specifically, medical physicist applicants must have successfully completed the applicable training and experience criteria described in 10 CFR Part 35 within 7 years preceding the date of the application. Alternatively, medical physicist applicants must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other recognized training pathways.

Response from Applicant: Provide the following:

- Name of the proposed AMP.

AND

- Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) on which the individual was specifically named as an AMP for the units requested.

OR

- Copy of the certification(s) for the board(s) recognized by NRC.

OR

- Description of the training and experience demonstrating that the proposed AMP is qualified by training and experience for the units requested. NRC Forms 313A and 313B may be used for this purpose (see Appendix G).

AND

- Written certification, signed by a preceptor AMP, that the above training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an AMP has been achieved.

Notes:

- Licensees must notify NRC within 30 days if an AMP permanently discontinues his or her duties under the license or has a name change under 10 CFR 35.14.
- Descriptions of training and experience will be reviewed using the criteria listed above. NRC will review the documentation to determine if the applicable criteria in Subpart B are met. If the training and experience do not appear to meet the Subpart B criteria, NRC may request additional information from the applicant or may request the assistance of its ACMUI in evaluating such training and experience. Referrals to the ACMUI are normally limited to new types of medical use not previously described in the regulations or guidance.

8.14 ITEM 8: SAFETY INSTRUCTION FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

Regulations: 10 CFR 19.12; 10 CFR 35.27; 10 CFR 35.310; 10 CFR 35.410; 10 CFR 35.610; 10 CFR 35.2310.

Criteria: Individuals working with or in the vicinity of licensed material must have adequate safety instruction as required by 10 CFR Parts 19 and 35. For individuals who, in the course of employment, are likely to receive in a year an occupational dose of radiation over 1 millisievert (mSv) [100 millirem (mrem)], the licensee must provide safety instructions as required by 10 CFR 19.12. Also, 10 CFR 35.310, 10 CFR 35.410, and 10 CFR 35.610 describe additional safety instruction requirements for individuals involved with therapeutic treatment of patients. Records of safety instruction provided must be maintained in accordance with 10 CFR 35.2310. 10 CFR 35.27 requires the licensee's AUs and ANPs to provide safety instruction to all personnel using byproduct material under their supervision.

Discussion: AUs, ANPs, AMPs, RSOs, and their supervised employees are most likely to receive doses in excess of 1 mSv (100 mrem) in a year. However, licensees also must evaluate potential radiation doses received by any individual working in or frequenting restricted areas. All individuals working with or around licensed materials should receive safety instruction commensurate with their assigned duties, and if it is likely that they could receive doses over 1 mSv (100 mrem) in a year, they must receive instruction as specified by 10 CFR 19.12. For example, a licensee might determine that housekeeping staff, while not likely to receive doses over 1 mSv (100 mrem), need to be informed of the nature of the licensed material and the meaning of the radiation symbol, and need to be instructed not to touch the licensed material and

to remain out of the room if the door to the licensed material storage location is open. Providing minimal instruction to ancillary staff (e.g., housekeeping, security, etc.) may assist in controlling abnormal events, such as loss of radioactive material.

In addition to safety instruction required by 10 CFR 19.12 and in accordance with 10 CFR 5.310, 10 CFR 35.410, and 10 CFR 35.610, the licensee must provide radiation safety instruction to personnel (e.g., nurses) caring for patients undergoing radiopharmaceutical therapy and/or implant therapy who cannot be released in accordance with 10 CFR 35.75. This safety instruction must be commensurate with the duties of the personnel and include safe handling, patient control, visitor control, contamination control, waste control, and notification of the RSO and the AU if the patient has a medical emergency or dies.

In accordance with 10 CFR 35.27(a), individuals working with licensed material under the supervision of an AU must receive instruction on the licensee's written radiation protection procedures, written directive procedures, and NRC regulations and license conditions with respect to the use of byproduct material.

In accordance with 10 CFR 35.27(b), a licensee that permits the preparation of byproduct material for medical use by an individual under the supervision of an ANP or an AU, as allowed by 10 CFR 35.11(b)(2), shall instruct supervised individuals in the preparation of byproduct material for medical use and require the individuals to follow their instructions, the licensee's written radiation protection procedures, the license conditions, and NRC regulations. 10 CFR 35.27(c) states that a licensee that permits supervised activities, under paragraph 10 CFR 35.27(a) and (b), is responsible for the acts and omissions of the supervised individuals.

A model training program is provided in Appendix H.

Response from Applicant: No response is necessary.

8.15 ITEM 9: FACILITIES AND EQUIPMENT

Regulations: 10 CFR 30.33(a)(2).

Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life or property.

Discussion: In 10 CFR 30.33(a)(2), NRC states that an application will be approved if, among other things, the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property. Facility and equipment requirements depend on the scope of the applicant's operations (e.g., planned use of the material, the types of radioactive emissions,

the quantity and form of radioactive materials possessed, etc.). Applicants should focus particularly on operations using large quantities of radioactive materials; preparation steps involving liquids, gases, and volatile radioactive materials; and the use of alpha-emitters, high-energy photon-emitters, and high-energy beta-emitters.

Response from Applicant: Refer to the subsequent sections for guidance.

8.16 ITEM 9: FACILITY DIAGRAM

Regulations: 10 CFR 20.1003; 10 CFR 20.1101; 10 CFR 20.1201; 10 CFR 20.1301; 10 CFR 20.1302; 10 CFR 20.1601; 10 CFR 20.1602; 10 CFR 20.1901; 10 CFR 20.1902; 10 CFR 20.2102; 10 CFR 30.32(b); 10 CFR 30.33(a)(2); 10 CFR 35.12; 10 CFR 35.14; 10 CFR 35.75; 10 CFR 35.315(a); 10 CFR 35.415; 10 CFR 35.615.

Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life or property.

Discussion: Applicants must describe the proposed facilities and equipment as required by 10 CFR 35.12 and must submit a facility diagram of the room or rooms (and adjacent areas) in which byproduct material will be received, prepared, used, administered, and stored. The diagram should be identified as ATT. 9.1. The areas to be represented in the diagram include rooms for patients hospitalized in accordance with 10 CFR 35.75; rooms used for preparing and administering radiopharmaceutical dosages or radiation doses; radioactive waste storage areas; and all byproduct material use areas, including those used for receipt and storage of the byproduct material. Pursuant to 10 CFR 20.1302, "Compliance with Dose Limits for Individual Members of the Public," licensees must demonstrate compliance with 10 CFR 20.1301, "Dose Limits for Individual Members of the Public," for unrestricted or controlled areas that are adjacent to rooms in which byproduct material will be received, used, administered, and stored. Figure 8.8 depicts a standard nuclear medicine suite.

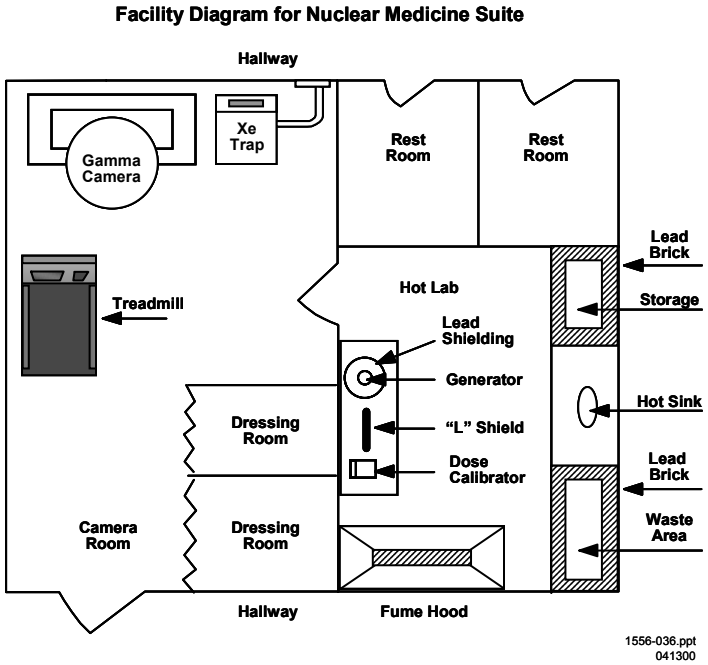

Figure 8.8 Facility Diagram for Nuclear Medicine Suite.

Regulatory requirements, the principle of ALARA, good medical care, and access control should be considered when determining the location of the therapy patient's room or a therapy treatment room. Use of byproduct material in a room that is not described in the license application requires prior NRC approval through a license amendment, except for areas of use where byproduct material is used in accordance with 10 CFR 35.100 and 10 CFR 35.200. Licensees must notify NRC, under 10 CFR 35.14, within 30 days following changes in areas of use for 10 CFR 35.100 and 10 CFR 35.200 byproduct material. Figure 8.9 presents a view of a radioiodine patient isolation room that contains some of the required elements discussed in the Response from Applicant section. Figure 8.10 presents an overhead view of a manual brachytherapy patient isolation room. Based on an evaluation of shielding and planned use of each area, the applicant must have determined whether each area adjacent to the treatment room will be maintained as a restricted or an unrestricted area, and must demonstrate compliance with NRC regulations. For portable shields, the licensee should assure proper placement of the shield prior to each treatment. Applicants must also submit facility diagrams to illustrate areas above, beside, and below the facilities used for patient therapy treatments (e.g., other patient rooms, stairwells, nursing stations, and waiting areas). To assist in the review of these areas, the diagrams should be cross-sectional. The radiation dose levels associated with these areas must comply with 10 CFR 20.1302, "Compliance with dose limits for individual members of the public." In addition, if radiopharmaceutical therapy and brachytherapy patient rooms are added after the initial license is issued, the additional room diagrams need to be submitted only if the room design (including shielding) and the occupancy of adjacent areas are significantly different from the original diagrams provided.

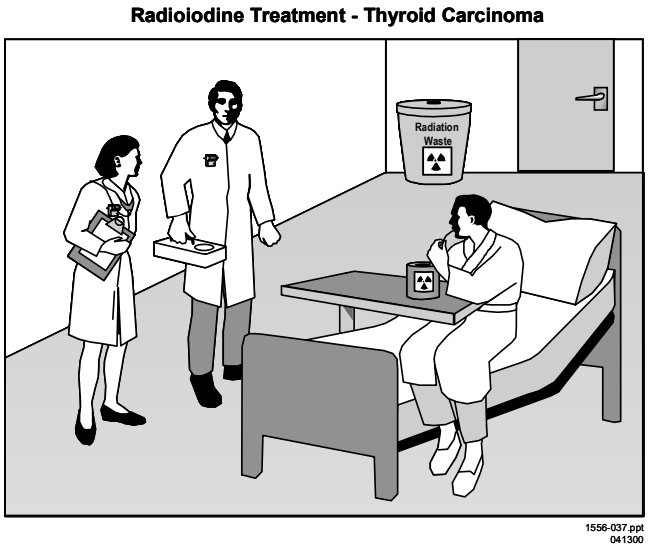

Figure 8.9 Iodine-131 NaI Administration for the Thyroid Carcinoma Patient. *The patient is required to be isolated in a private room (or with another radiopharmaceutical therapy patient) with a private bath.*

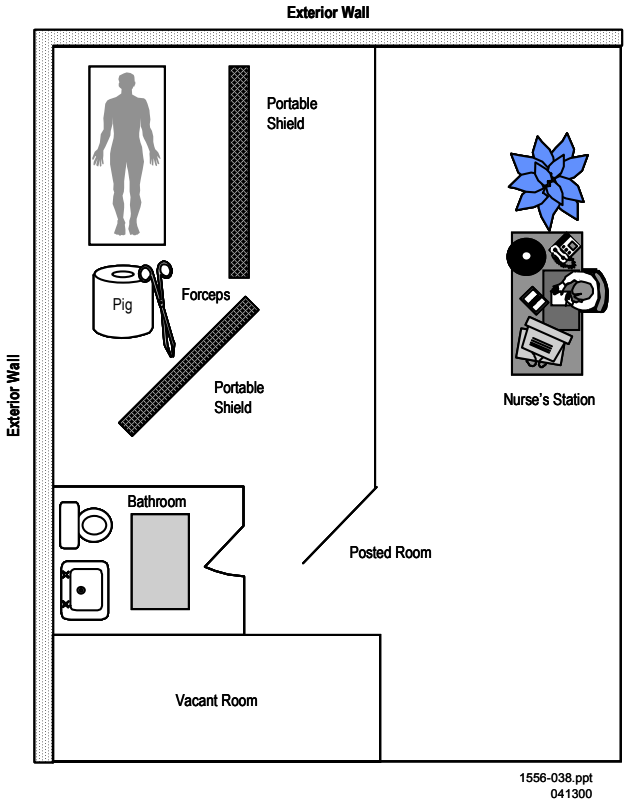

Figure 8.10 Overhead View of Manual Brachytherapy Patient Treatment Room.

Figure 8.11 represents a combined HDR and teletherapy suite. Based on an evaluation of shielding and the planned use of each area, the applicant must determine if each area adjacent to the treatment room used for all therapies involving sealed sources will be maintained as a restricted or an unrestricted area, and must demonstrate compliance with NRC regulations.

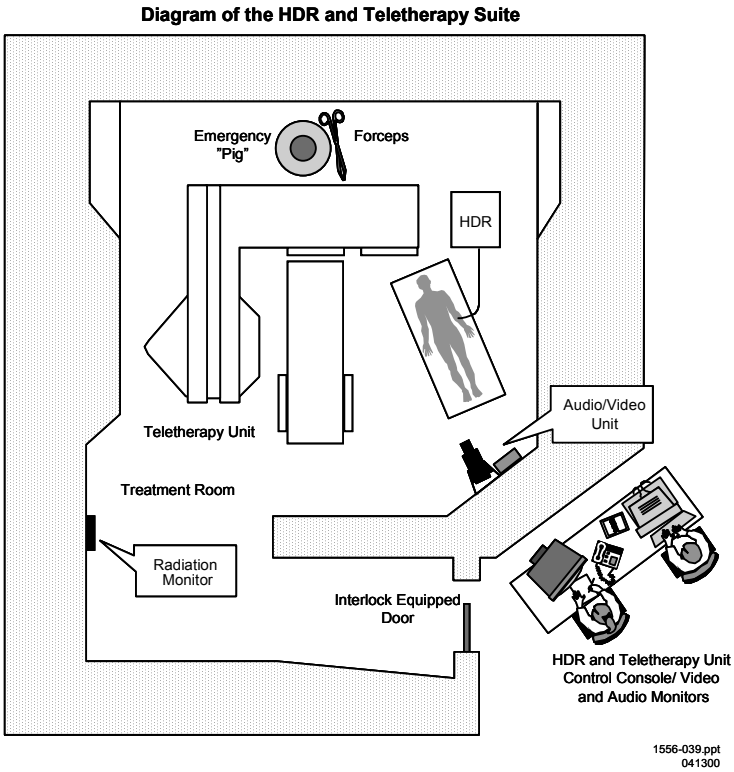

Figure 8.11 Teletherapy and HDR Treatment Room.

It may be necessary to restrict use of the teletherapy unit's primary beam if the treatment room's walls, ceiling, or floor will not adequately shield adjacent areas from direct or scattered radiation. Electrical, mechanical, or other physical means (rather than administrative controls) must be used to limit movement or rotation of the unit.

The teletherapy unit should be equipped with electrical or mechanical stops that limit use of the primary beam of radiation to ensure compliance with Subpart D of 10 CFR Part 20. Some applicants have found it helpful to have a sample response for guidance. The following is an example of an acceptable response on the use of a rotational unit with an integral beam absorber (also called a beam catcher); the angle orientation convention described above applies.

- "For the primary beam directed toward the integral beam absorber, electrical or mechanical stops are set so that the primary beam must be centered (within plus or minus 2 degrees) on the integral beam absorber and, in that configuration, the attenuated primary beam may be rotated 360 degrees pointing toward the floor, east wall, ceiling, and west wall."
- "For the primary beam directed away from the integral beam absorber, electrical or mechanical stops permit the unattenuated primary beam to be directed in a 95-degree arc from 5 degrees toward the west wall to vertically down toward the floor to 90 degrees toward the east wall."

Experience has shown that, given this type of example, many applicants can make changes to accommodate their own situations (e.g., use of a vertical unit, use of a rotational unit without an integral beam absorber).

Response from Applicant: Provide the following on the facility diagrams:

- Scale; use the same scale (preferably 1/4 inch = 1 foot) for all drawings;
- Direction of north;
- Location, room numbers, and principal use of each room or area where byproduct material is used or stored (e.g., patient therapy rooms, radioactive waste storage, nuclear medicine hot lab, manual brachytherapy source storage room);
- Location, room numbers, and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms, as well as if the room is restricted or unrestricted as defined in 10 CFR 20.1003;
- Type, thickness, and density of any necessary shielding applicable to the quantities, form, and emissions of the radionuclide that will be used, including a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy including the dimensions of any portable shield, if one is used; source storage safe, etc.) (***Note:*** beta emitters should be shielded using a material with a low atomic number to minimize the production of bremsstrahlung);
- Nature of and distances to all areas adjacent to therapy patient treatment rooms (including above, beside, and below), keeping in mind that plans are particularly helpful in showing the relationship of the patient treatment room to the rest of the building;
- Location of additional radiation safety equipment (e.g., fume hood, L-block, dose calibrator, fixed area monitors, remote handling tools, t-bars, Allen key) within the facility.

In addition to the above, for remote afterloader, teletherapy, and GSR facilities, applicants must provide information on the following:

- Type, thickness, and density of the shielding materials used on all sides of the treatment room, including the walls, floor, and ceiling;
- Location of doors, windows, conduits, and other penetrations and voids in the shielding materials;
- Nature of and distances to all areas adjacent to the treatment room (including above, beside, and below), with an indication of whether the areas are restricted or unrestricted, as defined in 10 CFR 20.1003, keeping in mind that plans and elevation drawings are particularly helpful in showing the relationships among the treatment room, the roof, and the rest of the building;
- Location of the treatment unit and source(s) within the treatment room.

In addition to the above, for teletherapy and GSR facilities, applicants must provide the following information:

- Directions of primary beam usage for teletherapy units and, in the case of an isocentric unit, the plane of beam rotation;
- Height of earth against outside walls, as applicable.

In addition to the facility description for remote afterloader units, provide detailed calculations of maximum radiation levels (and dose rates) that will exist in each area, restricted and unrestricted, adjacent to the room(s) where treatment is performed using a remote afterloader device, to demonstrate compliance with 10 CFR 20.1201 and 10 CFR 20.1301, respectively. (This includes areas above, beside, and below the treatment room.) The calculations should include the following:

- Expected radiation levels for each area adjacent to the room housing the device, taking into consideration the most adverse source orientations and maximum source activity to be used in the device. These calculations must be sufficient to demonstrate that the expected dose rates in restricted and unrestricted areas adjacent to the treatment room(s) meet the requirements of 10 CFR 20.1201 and 10 CFR 20.1301.
- Parameters (equations, constants, assumptions, etc.) used to perform the calculations described above. These parameters must include such factors as distance to each area of concern, the type and thickness of material(s) used in barriers and shields, the transmission factor of the barriers or shields, and the maximum source strength. For HDR and pulsed dose-rate (PDR) remote afterloader devices, the use of portable shielding to meet the dose rate requirements of 10 CFR 20.1201 and 10 CFR 20.1301 is not permitted.
- The maximum anticipated workload data, such as device maximum “on time” per hour and per week, and occupancy factors used for all adjacent areas.

- Determination of the dose received by individuals present in unrestricted areas, with calculations reflecting continuous occupancy (i.e., occupancy factor of 1), unless the applicant can justify using a lower value.
- Demonstration that the limits specified in 10 CFR 20.1301(a) will not be exceeded. If the calculations demonstrate that these limits cannot be met, indicate any further steps that will be taken to limit exposure to individual members of the public. The applicant may consider the following options:
  - — Adding shielding to the barrier in question, with corresponding modification of the facility description if necessary.
  - — Requesting prior NRC authorization to operate up to an annual dose limit for an individual member of the public of 5 mSv (0.5 rem) and demonstrating that the requirements of 10 CFR 20.1301 will be met. The applicant must demonstrate the need for and the expected duration of operations that will result in an individual dose in excess of the limits specified in 10 CFR 20.1301(a). A program to assess and control dose within the 5 mSv (0.5 rem) annual limit and procedures to be followed to maintain the dose ALARA (10 CFR 20.1101) must be developed.
  - — Decreasing exposure times and/or limiting the number of patient treatments or increasing the size of the restricted area surrounding the treatment room.

In addition to the facility description for teletherapy and GSR units, applicants must provide:

- A copy of the manufacturer's calculation of source(s) intensity;
- Calculations of the maximum radiation levels expected in each adjacent area, including the following:
  - — Maximum anticipated workload data (e.g., maximum number of patients treated per hour and per week, maximum dose and treatment time per patient, maximum on-time per hour and per week);
  - — The value of each parameter used in the calculations. These parameters include such factors as beam orientation, maximum field size, scatter angle, scatter ratio, distance to scatterer, distance to area of concern, type and thickness of materials used in barrier, and transmission factor of barrier;
  - — Contributions from primary, leakage (with the source in the on position), and scattered radiation (including low-angle scatter that just misses the integral beam absorber for teletherapy);
  - — Calculations for each area adjacent to the treatment room, including above, beside, and below the room, and a statement indicating if an area will be maintained as a restricted or

unrestricted area. Calculations need not be provided for areas that have not been excavated;

— Worst-case situations (e.g., use of maximum beam size; all patients treated in 1 hour using the critical orientation that produces high radiation levels in an adjacent area; if the teletherapy integral beam absorber is not used for all patient treatments, calculations based on use of the unattenuated primary beam where appropriate; situations within the capabilities of the teletherapy unit that are not prohibited by electrical or mechanical stops, regardless of the clinical usefulness of these orientations);

— The dose received by individuals present in unrestricted areas with continuous occupancy (i.e., occupancy factor of 1), unless the licensee can make a compelling argument for using a lower value.

- For each unrestricted area, a statement of how the requirements of 10 CFR 20.1301(a)(1) and (2) will be met;
- Description of the teletherapy unit's mechanical or electrical beam stops that restrict beam orientation, specify the direction in which the teletherapy head can be moved, and describe the maximum angle (from vertical) of the beam orientation in each direction. Identify the angle orientation convention (e.g., 0 degrees is vertical toward the floor, 90 degrees is horizontal toward the east wall, 180 degrees is vertical toward the ceiling, and 270 degrees is horizontal toward the west wall). If the teletherapy unit has an integral beam absorber (also called a beam catcher), provide similar information for those orientations in which: (1) the primary beam is directed toward the integral beam absorber; and (2) the primary beam is directed away from the integral beam absorber. Sketches may be used to describe how beam stops limit the use of the primary beam.

National Council on Radiation Protection and Measurements (NCRP) Report 49, "Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies up to 10 MeV," Report 102, "Medical X-Ray, Electron Beam and Gamma Ray Protection for Energies up to 50 MeV (Equipment Design, Performance and Use)", and Report 40, "Protection Against Radiation from Brachytherapy Sources" may be helpful in responding to the items above. In addition, NUREG/CR-6276, "Quality Management in Remote Afterloading Brachytherapy" and NUREG/CR-6324, "Quality Assurance for Gamma Knives" may also be helpful in responding to the items above. However, please note that references to 10 CFR Part 35 in the NUREGs may be inaccurate because the rule was amended after these documents were published.

8.17 ITEM 9: RADIATION MONITORING INSTRUMENTS

Regulations: 10 CFR 20.1101; 10 CFR 20.1501; 10 CFR 20.2102; 10 CFR 20.2103(a); 10 CFR 30.3; 10 CFR 30.33(a)(2); 10 CFR 35.27; 10 CFR 35.61; 10 CFR 35.2061.

Criteria: All licensees shall possess calibrated radiation detection and measuring instruments that will be used for radiation protection, including survey and monitoring instruments and quantitative measuring instruments needed to monitor the adequacy of radioactive materials containment and contamination control.

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with 10 CFR 20.1101 must include provisions for survey instrument calibration (10 CFR 20.1501). Licensees shall possess instruments used to measure radiation levels, radioactive contamination, and radioactivity, as applicable. Instruments used for quantitative radiation measurements must be calibrated for the radiation measured. The instruments must be available for use at all times when byproduct material is in use. The licensee must possess survey instruments sufficiently sensitive to measure the type and energy of radiation used, including survey instruments used to locate low energy or low activity seeds (e.g., I-125, Pd-103) if they become dislodged in the operating room or patient's room.

Usually, it is not necessary for a licensee to possess a survey meter solely for use during sealed source diagnostic procedures, since it is not expected that a survey be performed each time such a procedure is performed. In these cases, it is acceptable for the meter to be available on short notice in the event of an accident or malfunction that could reduce the shielding of the sealed source(s). Surveys may be required to verify source integrity of the diagnostic sealed source and to ensure that dose rates in unrestricted areas and public and occupational doses are within regulatory limits.

Survey meter calibrations must be performed by persons, including licensed personnel, who are specifically authorized by NRC or an Agreement State to perform calibrations. A licensee may use a calibration service if the service is licensed to perform these activities by an NRC (or an equivalent Agreement State) license. Applicants seeking authorization to perform survey meter calibrations must submit calibration facility diagrams in accordance with Section 8.16 of this document. Appendix I provides guidance regarding appropriate instrumentation and model survey instrument calibration procedures.

Response from Applicant: Provide the following:

- The instrument type, sensitivity, and range for each type of radiation detected, and, if applicants possess only one survey instrument to meet the criteria established in 10 CFR Part 35, a description of the procedures used when the survey instrument is being calibrated or repaired and either routine or emergency radiation surveys need to be performed.

AND

- A statement that: "Radiation monitoring instruments will be calibrated by a person authorized by NRC or an Agreement State to perform survey meter calibrations."

AND/OR

- A statement that: "We have developed and will implement and maintain written survey meter calibration procedures in accordance with the requirements in 10 CFR 20.1101 and that meet the requirements of 10 CFR 35.61."

References: See the Notice of Availability on the inside front cover of this report to obtain a copy of NUREG-1556, Vol. 18, "Program-Specific Guidance About Service Provider Licenses," dated November 2000.

8.18 ITEM 9: DOSE CALIBRATOR AND OTHER EQUIPMENT USED TO MEASURE DOSAGES OF UNSEALED BYPRODUCT MATERIAL

Regulations: 10 CFR 30.3; 10 CFR 30.33; 10 CFR 35.27; 10 CFR 35.41; 10 CFR 35.60; 10 CFR 35.63; 10 CFR 35.2060; 10 CFR 35.2063.

Criteria: In 10 CFR 35.60 and 10 CFR 35.63, NRC describes requirements for the use, possession, calibration, and check of instruments (e.g., dose calibrators) used to measure patient dosages.

Discussion: As described in 10 CFR 35.63, dosage measurement is required for licensees who prepare patient dosages. If the licensee uses only unit dosages made by a manufacturer or preparer licensed under 10 CFR 32.72, the licensee is not required to possess an instrument to measure the dosage. Furthermore, licensees who receive unit dosages of byproduct material and do not split the dosages may rely on the provider's dose label for the measurement of the dosage and decay-correct the dosage to the time of administration. However, pursuant to 10 CFR 35.60, if the licensee performs direct measurements of dosages in accordance with 10 CFR 35.63 (e.g., prepares its own dosages, breaks up unit dosages for patient administration, or decides to measure unit dosages) the licensee is required to possess and calibrate all instruments used for measuring patient dosages. Appendix J provides model dose calibrator calibration procedures. Currently, no alpha-emitting nuclides are used in unsealed form in medicine. This document does not, therefore, provide guidance on the measurement of these radionuclides.

Equipment used to measure dosages that emit gamma, alpha, or beta radiation must be calibrated in accordance with nationally recognized standards (e.g., ANSI) or the manufacturer's instructions. The measurement equipment may be a well ion chamber, a liquid scintillation counter, etc., as long as the instrument is accurate, reliable, and able to be calibrated appropriately.

For other than unit dosages, the activity must be determined by direct measurement, by a combination of radioactivity measurement and mathematical calculation, or by a combination of volumetric measurement and mathematical calculation. However, there are inherent technical difficulties to overcome. For beta-emitting radionuclides, these difficulties include dependence on geometry, lack of an industry standard for materials used in the manufacture of vials and syringes, and lack of a NIST-traceable standard for all radionuclides used. For instance, when determining the dosage of P-32, assays with a dose calibrator may result in inaccuracies caused by inherent variations in geometry; therefore, a volumetric measurement and mathematical calculation may be more accurate. Licensees must assay patient dosages in the same type of vial and geometry as used to determine the correct dose calibrator settings. Using different vials or syringes may result in measurement errors due, for example, to the variation of bremsstrahlung created by interaction between beta particles and the differing dosage containers. Licensees are reminded that beta emitters should be shielded using a low-atomic-numbered material to minimize the production of bremsstrahlung, followed by a high-atomic-numbered material thick enough to attenuate the bremsstrahlung intensity.

Dosage measuring equipment may be calibrated by persons authorized by NRC or an Agreement State to perform such services. For example, a licensee may use a calibration service if the service is licensed to perform these activities by NRC (or an equivalent Agreement State) license.

Response from Applicant: If applicable, provide the following:

- A statement that: "Equipment used to measure dosages of unsealed byproduct material will be calibrated by a person authorized by NRC or an Agreement State to perform dosage measuring equipment calibrations."

AND/OR

- A statement that: "We have developed and will implement and maintain written calibration procedures for equipment used to measure dosages of unsealed byproduct material in accordance with 10 CFR 35.41, and that meet the requirements in 10 CFR 35.60 and 10 CFR 35.63, as applicable."

AND

- Instrument type and, if only one dose calibrator is possessed, a description of procedures used when the dose calibrator is being calibrated or repaired and patient dosages need to be measured.

8.19 ITEM 9: DOSIMETRY EQUIPMENT – CALIBRATION AND USE

Regulations: 10 CFR 30.33(a)(2); 10 CFR 35.27; 10 CFR 35.41; 10 CFR 35.432; 10 CFR 35.630; 10 CFR 35.632; 10 CFR 35.633; 10 CFR 35.635; 10 CFR 35. 642; 10 CFR 35.643; 10 CFR 35.645; 10 CFR 35.2432; 10 CFR 35.2630; 10 CFR 35.2632; 10 CFR 35.2642; 10 CFR 35.2643; 10 CFR 35.2645.

Criteria: The above regulations contain NRC requirements, including recordkeeping requirements, for verification and periodic spot-checks of source activity or output. To perform these measurements, the applicant must possess appropriately calibrated dosimetry equipment.

Discussion: Except for brachytherapy sources and low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer in accordance with 10 CFR Part 35, the applicant must possess a calibrated dosimetry system (e.g., Farmer chamber, electrometer, well-type ionization chamber) that will be used to perform calibration measurements of sealed sources to be used for patient therapy. Dosimetry systems and/or sealed sources used to calibrate the licensee's dosimetry systems must be traceable to NIST or to a laboratory accredited by AAPM, pursuant to 10 CFR 35.630. The licensee must maintain records of calibrations for the duration of the license.

The licensee's AMP must perform full calibrations of sealed sources and devices used for therapy in accordance with published protocols accepted by nationally recognized bodies (e.g., ANSI). (Note: An AMP is not specified for brachytherapy sources.) The licensee's AMP must calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. In addition, the licensee must perform spot-check measurements of sealed sources and devices used for therapy in accordance with written procedures established by the AMP (10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645). The calibration procedures described in AAPM Task Group Nos. 21, 40 or 56, and Report 54, or any published protocol approved by a nationally recognized body, as applicable, may be used. The calibration procedures should address, in part:

- The method used to determine the exposure rate (or activity) under specific criteria (i.e., distances used for the measurement, whether the measurement is an "in air" measurement or done using a phantom configuration of the chamber with respect to the source(s) and device, scatter factors used to compute the exposure rate, etc.).
- A commitment to maintain a record of calibration measurements and associated calculations.

Full calibrations, as described in greater detail in Section 8.41, must be performed before first medical use[3], whenever spot-check measurements (if required) indicate that the output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for decay, following replacement of the sources or reinstallation of the unit in a new location not previously described in the license, following any repairs of the unit that include removal of sealed sources or major repair of the components associated with the source exposure assembly, and at intervals as defined in 10 CFR 35.632, 10 CFR 35.633, and 10 CFR 35.635. Manual brachytherapy sources must be calibrated only initially, prior to use.

Response from Applicant: Provide the following:

- A statement that: "We will calibrate dosimetry equipment in accordance with the requirements in 10 CFR 35.630."

AND

- A statement that: "We have developed and will implement and maintain written therapy sealed source calibration and spot-check procedures in accordance with 10 CFR 35.41 that meet the requirements in 10 CFR 35.432, 10 CFR 35.632, 10 CFR 35.633, 10 CFR 35.635, 10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645 (as applicable to the type of medical use requested)."

AND

- Identification of the instrument type, manufacturer, and model number.

References: Copies of AAPM Task Group No. 21, "A Protocol for the Determination of Absorbed Dose from High-Energy Photon and Electron Beams," AAPM Task Group No. 40, "Comprehensive QA for Radiation Oncology," AAPM Report No. 54, "Stereotactic Radiosurgery," AAPM Task Group No. 56, "Code of Practice for Brachytherapy Physics," may be obtained from the American Association of Physicists in Medicine, One Physics Ellipse, College Park, MD 20740-3843 or by ordering electronically from <http://www.aapm.org>.

8.20 ITEM 9: OTHER EQUIPMENT AND FACILITIES

Regulations: 10 CFR 20.1101; 10 CFR 30.33(a)(2); 10 CFR 30.34; 10 CFR 35.12; 10 CFR 35.315; 10 CFR 35.415; 10 CFR 35.457; 10 CFR 35.615; 10 CFR 35.647; 10 CFR 35.657.

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[3] For brachytherapy sources, "before first medical use" is defined as the first use following the effective date of the revised 10 CFR Part 35.

Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life or property.

Discussion: The applicant must describe, in Item 9 of the application, other equipment and facilities available for safe use and storage of byproduct material listed in Item 5 of this application (e.g. fume hoods, xenon traps, emergency response equipment, area monitors, remote handling tools, source transport containers, patient viewing and intercom systems, interlock systems). This description should be identified as ATT. 9.4.

The applicant must describe additional facilities and equipment for the **radiopharmaceutical therapy program** to safely receive, use, store, and dispose of radioactive material. The applicant should focus on facilities to be used for radioactive drug therapy administration and patient accommodations (i.e., private room with private bath). I-131 sodium iodide is the most widely used source of radiopharmaceutical therapy. If the radionuclide is administered in liquid form, it is important to place the patient dosage in a closed environment (i.e., a fume hood) because of the volatility of the radiopharmaceutical. If the patient has exceeded the release limits of 10 CFR 35.75, the patient must be accommodated in a room with a private bath as described in Section 8.16 of this document. Sources of patient contamination include airborne I-131 and radioactivity in the patient's urine, perspiration, and saliva.

To facilitate decontamination of the patient's room, floors, toilet areas, sink areas, countertops, and other permeable surfaces, the licensee should consider covering areas with disposable materials having plastic on one side and absorbent material on the other. In addition, items handled by the patient may be covered with plastic. These items include the telephone, faucet and toilet handles, television remote control, door handles, and nurse call buttons. P-32 is effectively shielded by a plastic syringe and once the radionuclide has been administered to the patient, there is no external radiation hazard; therefore, P-32 does not require that the patient be placed in isolation. However, P-32 administered in colloidal form can contaminate bandages and dressings; therefore, designated waste containers should be kept in the patient room.

For **teletherapy, GSR, and HDR facilities**, the licensee shall require any individual entering the treatment room to ensure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels. A beam-on radiation monitor permanently mounted in each therapy treatment room that is equipped with an emergency power supply separate from the power supply for the therapy unit meets the requirements of 10 CFR 35.615(c). In addition, the beam-on monitors traditionally installed in therapy treatment rooms can provide a visible indication (e.g., flashing light) of an exposed or partially exposed source.

The applicant shall describe the system, required by 10 CFR 35.615(d), used to view and communicate with the patient continuously while the patient is in the treatment room. If a shielded viewing window will be used, the thickness, density, and type of material used shall be

specified. If a closed-circuit television system (or some other electronic system) will be used to view the patient, the backup system or procedure to be used in case the electronic system malfunctions shall be specified, or the applicant must commit to suspending all treatments until the electronic system is repaired and functioning again. The communication system must allow the patient to communicate with the unit operator in the event of medical difficulties. An open microphone system is recommended to allow communication without requiring the patient to move to activate controls.

The applicant must also provide adequate equipment and controls to maintain exposures of radiation to workers ALARA and within regulatory limits. 10 CFR 35.615(b), in part, requires that each door leading into the treatment room be provided with an electrical interlock system to control the on-off mechanism of the therapy unit. The interlock system must cause the source(s) to be shielded if the door to the treatment room is opened when the source is exposed. The interlock system must also prevent the operator from initiating a treatment cycle unless the treatment room entrance door is closed. Additionally, the interlock must be wired so that the source(s) cannot be exposed after interlock interruption until the treatment room door is closed and the source(s) on-off control is reset at the console.

Due to the unique characteristics of **PDR remote afterloaders** and the lack of constant surveillance of their operation, a more sophisticated alarm system is essential to ensure the patient is protected during treatment. In addition to the above, it is necessary, under 10 CFR 20.1801, 10 CFR 30.33, 10 CFR 30.34, 10 CFR 35.41, and 10 CFR 35.615, to ensure the following:

- The PDR device control console is *not* accessible to unauthorized personnel during treatment;
- A primary care provider checks the patient to ensure that the patient's device has not been moved, kinked, dislodged, or disconnected;
- A more sophisticated interlock/warning system is normally installed for PDR devices. This system should perform the following functions or possess the following characteristics:
  - — The signal from the PDR device and the signal from the room radiation monitor should be connected in such a manner that an audible alarm sounds if the room monitor indicates the presence of radiation and the device indicates a "safe" or retracted position;
  - — The alarm circuit should also be wired in such a manner that an audible alarm is generated for any device internal error condition that could indicate the unintended extension of the source. This would constitute a circuit that generates the audible alarm when either the "source retracted and radiation present" or appropriate internal error condition(s) exist;
  - — The "source safe and radiation present" signal should also be self-testing. If a "source not safe" input is received without a corresponding "radiation present" signal, the circuit

should generate an interlock/warning circuit failure signal that will cause the source to retract. This circuit will require manual resetting before attempting to continue treatment;

— The audible alarm should be sufficiently loud to be clearly heard by the facility's responsible device/patient monitoring staff at all times;

— No provisions for bypassing this alarm circuit or for permanently silencing the alarm should be made to the circuit as long as the room radiation monitor is indicating the presence of radiation. If any circuitry is provided to mute the audible alarm, such circuitry should not mute the alarm for a period of more than 1 minute. Controls that disable this alarm circuit or provide for silencing the alarm for periods in excess of 1 minute should be prohibited.

If the alarm circuit is inoperative for any reason, a licensee should prohibit initiating any patient treatments with the device until the circuit has been repaired and tested. If the alarm circuit fails during the course of a patient treatment, the treatment in progress may continue as long as continuous surveillance of the device is provided during each treatment cycle or fraction.

For patient rooms where **low dose-rate (LDR) remote afterloader** use is planned, neither a viewing nor an intercom system is required. However, the applicant should describe how the patient and device will be monitored during treatment to ensure that the sources and catheter guide tube are not disturbed during treatment and to provide for prompt detection of any operational problems with the LDR device during treatment.

Response from Applicant: Provide a description of additional facilities and equipment required by the applicable section of 10 CFR Parts 30 and 35 (e.g., 10 CFR 20.1101, 10 CFR 30.33(a)(2), 10 CFR 30.34, 10 CFR 35.12, 10 CFR 35.315, 10 CFR 35.415, 10 CFR 35.457, 10 CFR 35.615, 10 CFR 35.647, and 10 CFR 35.657). For teletherapy, GSR, and remote afterloader facilities, include a description of the:

- Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room;
- Methods for controlling occupancy for each restricted area;
- Area radiation monitoring equipment;
- Viewing and intercom systems (except for LDR units);
- Steps that will be taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment (e.g., linear accelerator, x-ray machine) are in the treatment room;
- Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons.

8.21 ITEM 10: RADIATION PROTECTION PROGRAM

Regulations: 10 CFR 20.1101; 10 CFR 20.2102; 10 CFR 30.33; 10 CFR 30.34(e); 10 CFR 35.24; 10 CFR 35.26; 10 CFR 35.2024; 10 CFR 35.2026.

Criteria: 10 CFR 20.1101 states that each licensee must develop, document, and implement a radiation protection program commensurate with the scope of the licensed activity. The program must be sufficient to ensure compliance with the provisions of Part 20 regulations. The licensee is responsible for the conduct of all licensed activities and the acts and omissions of individuals handling licensed material. 10 CFR 30.34(e) provides that NRC may incorporate into byproduct material licenses, at the time of issuance or thereafter, additional requirements and conditions that it deems appropriate or necessary to, in part, protect health or to minimize danger to life and property. 10 CFR 35.24 describes the licensee management's authorities and responsibilities for the radiation protection program. 10 CFR 35.26 sets forth four circumstances in which the licensee may revise its radiation protection program without NRC approval, including when the revision does not require a license amendment (e.g., replacement of survey instruments with comparable survey instruments).

Discussion: Applicants/licensees must abide by all applicable regulations, develop, implement, and maintain procedures when required, and/or provide requested information about the proposed radiation protection program during the licensing process. The table in Appendix C may be helpful in determining what information must be provided when requesting a license. The applicant/licensee should consider the following functional areas (as applicable to the type of medical program):

- Audit program;
- Occupational dose;
- Public dose;
- Minimization of contamination;
- Operating and emergency procedures;
- Material receipt and accountability:
  - — Ordering and receiving
  - — Opening packages
  - — Sealed source inventory
  - — Use records;
- Leak tests;

- Area surveys;
- Procedures for administrations requiring a written directive;
- Safe use of unsealed licensed material;
- Installation, maintenance, adjustment, repair, and inspection of therapy devices containing sealed sources;
- Spill procedures;
- Emergency response for sealed sources or devices containing sealed sources;
- Patient or human research subject release;
- Safety procedures for therapy treatments where patients are hospitalized;
- Procedures for device calibration, safety checks, operation, and inspection;
- Mobile medical service;
- Transportation;
- Waste management.

Response From Applicant: Respond to subsequent sections of this document regarding Items 10 and 11 of the application.

8.22 ITEM 10: AUDIT PROGRAM

Regulations: 10 CFR 20.1101; 10 CFR 20.2102.

Criteria: Under 10 CFR 20.1101, licensees must annually review the content and implementation of the radiation protection program. The review should ensure the following:

- Compliance with NRC and DOT regulations (as applicable), and the terms and conditions of the license;
- Occupational doses and doses to members of the public are ALARA (10 CFR 20.1101);
- Records of reviews and/or audits and other reviews of radiation protection program content are maintained for 3 years after the record is made.

Discussion: The applicant should develop and implement procedures for the required review and/or audit of the radiation protection program's content and implementation. Appendix K contains model procedures. All areas indicated in Appendix K may not apply to every licensee and may not need to be addressed during each review and/or audit. For example, licensees do

not need to address areas that do not apply to their activities, and activities that have not occurred since the last review and/or audit need not be reviewed at the next review and/or audit. Reviews and/or audits of the radiation protection program must be conducted periodically (at least annually).

NRC encourages licensee management to conduct performance-based audits by observing work in progress, interviewing staff about the radiation protection program, and spot-checking required records. As part of their review and/or audit programs, licensees should consider performing unannounced audits of authorized and supervised users to determine if, for example, Operating and Emergency Procedures are available and are being followed.

It is essential that once identified, violations and radiation safety concerns are corrected comprehensively and in a timely manner. IN 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," dated May 1, 1996, provides guidance on this subject, and specifically describes a three-step corrective action process:

1. Conduct a complete and thorough review of the circumstances that led to the violation.
2. Identify the root cause of the violation.
3. Take prompt and comprehensive corrective actions that will address the immediate concerns and prevent recurrence of the violation.

NRC will review the licensee's review and/or audit results and determine if corrective actions are thorough, timely, and sufficient to prevent recurrence. Depending on the significance of the violation, if the violation is identified by the licensee and the three corrective steps are taken, NRC may exercise discretion and may elect not to cite a violation. NRC's goal is to encourage prompt identification and prompt, comprehensive correction of violations and deficiencies.

For additional information on NRC's use of discretion on issuing a notice of violation, refer to NUREG-1600, "General Statement of Policy and Procedures for NRC Enforcement Actions."

Under 10 CFR 20.2102, licensees must maintain records of audits and other reviews of radiation protection program content and implementation for 3 years from the date of the record. Audit records should contain audit findings, noted deficiencies, and corrective actions.

Response from Applicant: The applicant is not required to, and should not, submit its audit program to NRC for review.

References: See the Notice of Availability on the inside front cover of this report to obtain copies of: NUREG-1600, "General Statement of Policy and Procedures on NRC Enforcement Actions," and IN 96-28, "Suggested Guidance Relating to Development and Implementation of

Corrective Action," dated May 1, 1996. NUREG-1600 is also available on the Internet at NRC's web site, <http://www.nrc.gov>, under "Nuclear Materials" and "Enforcement."

8.23 ITEM 10: OCCUPATIONAL DOSE

Regulations: 10 CFR 20.1101; 10 CFR 20.1201; 10 CFR 20.1202; 10 CFR 20.1204; 10 CFR 20.1207; 10 CFR 20.1208; 10 CFR 20.1501; 10 CFR 20.1502; 10 CFR 20.2102; 10 CFR 20.2106; 10 CFR 35.27.

Criteria: Applicants must do either of the following:

- Demonstrate that unmonitored individuals are not likely to receive, in 1 year, a radiation dose in excess of 10 % of the allowable limits as shown in Figure 8.12.

OR

- Monitor external and/or internal occupational radiation exposure, if required by 10 CFR Part 20.1502.

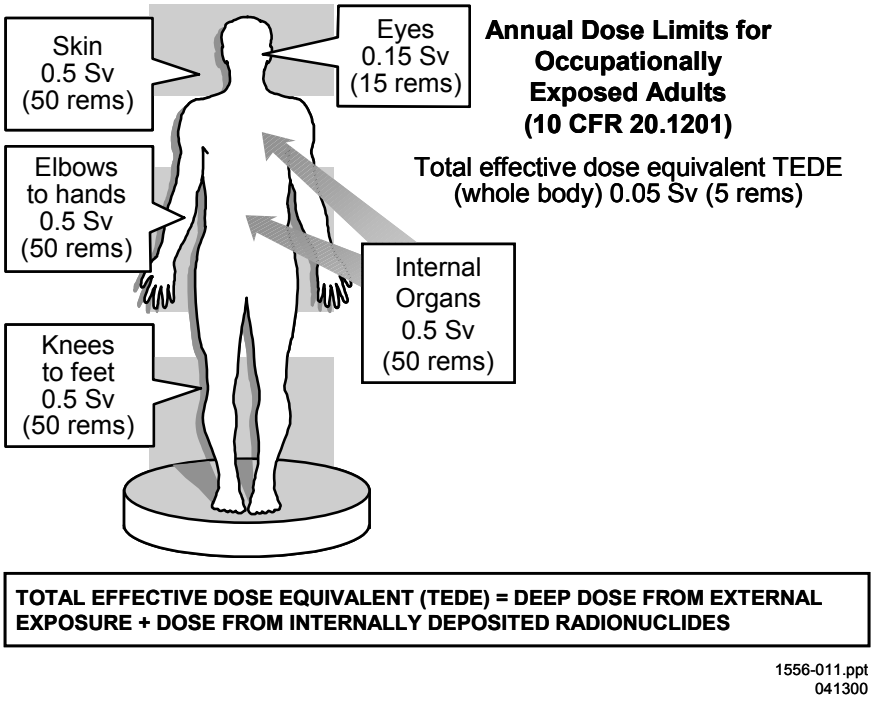

Figure 8.12 Annual Occupational Dose Limits for Adults.

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with 10 CFR 20.1101, must include provisions for monitoring occupational dose. The licensee must evaluate the exposure of all occupational workers (e.g., nurses, technologists) to determine if monitoring is required to demonstrate compliance with Subpart F of 10 CFR Part 20. Licensees must consider the internal and external dose and the occupational workers' assigned duties when evaluating the need to monitor occupational radiation exposure.

When evaluating external dose from xenon gas, the licensee may take credit for the reduction of dose resulting from the use of xenon traps. Additionally, periodic checks of the trap effluent may be used to ensure proper operation of the xenon trap. Licensees may vent xenon gas directly to the atmosphere as long as the effluent concentration is within 10 CFR Part 20 limits.

When evaluating dose from aerosols, licensees may take credit for the reduction of dose resulting from the use of aerosol traps. Licensees may vent aerosols directly to the atmosphere as long as the effluent concentration is within 10 CFR Part 20 limits.

Appendix L provides a model procedure for monitoring external occupational exposure.

If external dose monitoring is necessary, the applicant should describe the type of personnel dosimetry, such as film badges, optically stimulated luminescence dosimeters (OSL), and thermoluminescent dosimeters (TLDs), that personnel will use. If occupational workers handle licensed material, the licensee should evaluate the need to provide extremity monitors, which are required if workers are likely to receive a dose in excess of 0.05 Sv (5 rem) shallow-dose equivalent (SDE), in addition to whole-body badges. Additionally, applicants should ensure that their personnel dosimetry program contains provisions that personnel monitoring devices be worn so that the part of the body likely to receive the greatest dose will be monitored.

Some licensees use self-reading dosimeters in lieu of processed dosimetry. This is acceptable if the regulatory requirements are met. See American National Standards Institute (ANSI) N322, "Inspection and Test Specifications for Direct and Indirect Reading Quartz Fiber Pocket Dosimeters," for more information. If pocket dosimeters are used to monitor personnel exposures, applicants should state the useful range of the dosimeters, along with the procedures and frequency for their calibration and maintenance as required by 10 CFR 20.1501(b).

When personnel monitoring is needed, most licensees use either film badges or TLDs that are supplied by a processor holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP). Film badges are usually exchanged monthly due to technical concerns about film fading. TLDs are usually exchanged quarterly. Under 10 CFR 20.1501, licensees must verify that the processor is accredited by NVLAP for the

type of radiation for which monitoring will be performed. Consult the NVLAP-accredited processor for its recommendations for exchange frequency and proper use.

It may be necessary to assess the intake of radioactivity for occupationally exposed individuals in accordance with 10 CFR 20.1204 and 20.1502. If internal dose monitoring is necessary, the applicant must measure the following:

- Concentrations of radioactive material in air in work areas;
- Quantities of radionuclides in the body;
- Quantities of radionuclides excreted from the body; or
- Combinations of these measurements.

For example, for individuals preparing or administering therapeutic dosages of I-131, licensees may need to assess thyroid burden measurements. For individuals who are occupationally exposed to lesser quantities of I-131, RG 8.20, "Applications of Bioassay for I-125 and I-131, Revision 1," suggests frequencies of bioassays for individuals, based on quantities handled, type of compounds (volatile/non-volatile), and facilities used.

The applicant should describe in its procedures the criteria used to determine the type of bioassay and the frequencies at which bioassay (both *in vivo* and *in vitro*) will be performed to evaluate intakes. The criteria also should describe how tables of investigational levels are derived, including the methodology used by the evaluated internal dose assessments, i.e., the empirical models used to interpret the raw bioassay data. The bioassay procedures should provide for baseline, routine, emergency, and follow-up bioassays. Under 10 CFR 30.33(a)(2), the applicant must describe the equipment and facilities dedicated to the bioassay program required by 10 CFR 20.1501. If a commercial bioassay service will be used, the applicant must ensure that the service is licensed to perform these activities by an NRC (or an equivalent Agreement State) license.

RG 8.9, Revision 1, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program," and NUREG/CR-4884, "Interpretation of Bioassay Measurements," outline acceptable criteria that applicants may use in developing their bioassay programs.

10 CFR 20.1202 describes the requirements for summing external and internal doses. Applicants must ensure that their occupational monitoring procedures include criteria for summing external and internal doses.

Response from Applicant: Provide the following:

- A description of facilities and equipment used for monitoring occupational exposure.

AND

- A statement that: "We have developed and will implement and maintain written procedures for monitoring occupational dose in accordance with 10 CFR 20.1101 that meet the requirements in Subparts C and F of 10 CFR Part 20."

References: National Institute of Standards and Technology (NIST) Publication 810, "National Voluntary Laboratory Accreditation Program Directory," is published annually and is available for purchase from GPO and on the Internet at <http://ts.nist.gov/ts/htdocs/210/214/dosim.htm>. Copies of ANSI N322 may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018, or ordered electronically from <http://www.ansi.org>. See the Notice of Availability on the inside front cover of this report to obtain copies of RG 8.20, "Applications of Bioassay for I-125 and I-131, Revision 1," RG 8.9, Revision 1, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program," and NUREG/CR-4884, "Interpretation of Bioassay Measurements."

8.24 ITEM 10: PUBLIC DOSE

Regulations: 10 CFR 20.1301; 10 CFR 20.1302; 10 CFR 20.1801; 10 CFR 20.1802; 10 CFR 20.2107.

Criteria: Licensees must do the following:

- Ensure that licensed material will be used, transported, and stored in such a way that members of the public will not receive more than 1 mSv (100 mrem) in 1 year, and the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any one hour from licensed operations.
- Control and maintain constant surveillance of licensed material that is not in storage and secure stored licensed material from unauthorized access, removal, or use.

Discussion: Members of the public include persons who are not radiation workers. This includes workers who work or may be near locations where licensed material is used or stored and employees whose assigned duties do not include the use of licensed materials and who work in the vicinity where it is used or stored (see Figure 8.13). Public dose is controlled, in part, by ensuring that licensed material is secure (e.g., located in a locked area) to prevent unauthorized access or use by individuals coming into the area. Some medical use devices containing licensed material are usually restricted by controlling access to the keys needed to operate the devices

and/or to keys to the locked storage area. Only AUs and personnel using byproduct material under their supervision should have access to these keys.

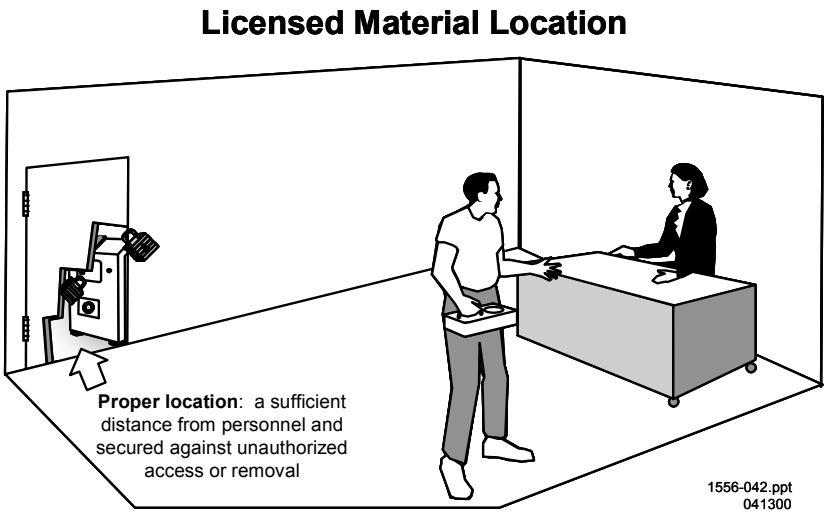

Figure 8.13 Proper Security of Licensed Material. *Licensed Material should be located away from occupied areas and secured to prevent unauthorized use or removal.*

Public dose is also affected by the choice of storage and use locations and conditions. Licensed material may present a radiation field and must be located so that the public dose in an unrestricted area (e.g., an office or the exterior surface of an outside wall) does not exceed 1 mSv (100 mrem) in a year or 0.02 mSv (2 mrem) in any one hour. Licensees should use the concepts of time, distance, and shielding when choosing storage and use locations. Decreasing the time, increasing the distance, and using shielding (i.e., brick, concrete, lead, or other solid walls) will reduce the radiation exposure.

Licensees can determine the radiation levels adjacent to licensed material either by direct measurement, calculations or a combination of direct measurements and calculations using some or all of the following: typical known radiation levels provided by the manufacturer, the "inverse square" law to evaluate the effect of distance on radiation levels, occupancy factor to account for the actual presence of the member of the public, and limits on the use of licensed material. See Appendix M for an example demonstrating that individual members of the public will not receive doses exceeding the allowable public dose limits.

If, after making an initial evaluation, a licensee changes the conditions used for the evaluation (e.g., the location of licensed material within a designated room, the type or frequency of licensed material use, or the occupancy of adjacent areas), the licensee must perform a new evaluation to ensure that the public dose limits are not exceeded and take corrective action, as needed.

Response from Applicant: No response is required from the applicant in a license application except as provided in response to Section 8.16, but this matter will be examined during inspection. During NRC inspections, licensees must be able to provide documentation demonstrating, by measurement, calculation, or both, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public. See Appendix M for examples of methods that demonstrate compliance with public dose limits.

8.25 ITEM 10: MINIMIZATION OF CONTAMINATION

Regulations: 10 CFR 20.1406; 10 CFR 35.67.

Criteria: Applicants for new licenses must describe in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

Discussion: All applicants for new licenses need to consider the importance of designing and operating their facilities to minimize the amount of radioactive contamination generated at the site during its operating lifetime and to minimize the generation of radioactive waste during decontamination. This is especially important for licensed activities involving unsealed byproduct material. As described in Item 8.37, "Spill Procedures," cleanup procedures should be implemented for any contamination event. Also, as described in Appendix R, Tables R.2 and R.3 provide recommendations on the acceptable surface contamination levels in restricted and unrestricted areas.

Sealed sources and devices that are approved by NRC or an Agreement State and located and used according to their SSDR Certificates usually pose little risk of contamination. Leak tests performed as specified in the SSDR Certificate should identify defective sources. Leaking sources must be immediately withdrawn from use and stored, repaired, or disposed of according to NRC requirements. These steps minimize the spread of contamination and reduce radioactive waste associated with decontamination efforts. Other efforts to minimize radioactive waste do not apply to programs using only sealed sources and devices that have not leaked.

Response from Applicant: Provide a description of how facility design and procedures for operation will minimize contamination of the facility and the environment, facilitate eventual decommissioning, and minimize the generation of radioactive waste.

8.26 ITEM 10: OPERATING AND EMERGENCY PROCEDURES

Regulations: 10 CFR 19.11(a)(3); 10 CFR 20.1101; 10 CFR 20.1601; 10 CFR 20.1602; 10 CFR 20.1801; 10 CFR 20.1802; 10 CFR 20.1906; 10 CFR 20.2102; 10 CFR 20.2201-2203; 10 CFR 21.21; 10 CFR 30.34(e); 10 CFR 30.50; 10 CFR 35.27; 10 CFR 35.41; 10 CFR 35.75; 10 CFR 35.310; 10 CFR 35.315; 10 CFR 35.404; 10 CFR 35.406; 10 CFR 35.410; 10 CFR 35.415; 10 CFR 35.610; 10 CFR 35.615; 10 CFR 35.3045; 10 CFR 35.3047; 10 CFR 35.3067.

Criteria: When using licensed material, licensees must do the following:

- Develop, implement, and maintain specific operating and emergency procedures containing the following elements:
  - — Instructions for opening packages containing licensed material, using licensed material, operating therapy treatment devices, and performing routine maintenance on devices containing sealed sources, according to the manufacturer's written recommendations and instructions and in accordance with regulatory requirements;
  - — Instructions for conducting area radiation level and contamination surveys;
  - — Instructions for administering licensed material in accordance with the WD;
  - — Steps to take, and whom to contact (e.g., RSO, local officials), when the following has occurred: (a) leaking or damaged source, (b) device malfunction and/or damage, (c) licensed material spills, (d) theft or loss of licensed material, or (e) any other incidents involving licensed material;
  - — Steps for source retrieval and access control of damaged sealed source(s) and/or malfunctioning devices containing sealed source(s);
  - — Steps to ensure that patient release is in accordance with 10 CFR 35.75;
  - — Steps to take if a therapy patient undergoes emergency surgery or dies;
  - — Instructions for calibration of survey and dosage measuring instruments;
  - — Periodic spot checks of therapy device units, sources, and treatment facilities;
  - — Instructions for radioactive waste management.

AND

- Make operating procedures, including emergency procedures, available to all users (e.g., post the procedures or the location of procedure storage);
- Maintain a current copy of the procedures at each location of use (or, if this is not practicable, post a notice describing the procedures and stating where they may be examined).

When developing the procedures described above, the licensee is reminded that 10 CFR 20.1101(b) requires that the licensee use, to the extent practical, procedures and engineering controls based on sound radiation protection principles to achieve occupational doses and doses to members of the public that are ALARA. In addition, when receiving and using byproduct material, the licensee is reminded that it must be licensed to possess the byproduct material and that the radioactive material must be secured (or controlled) and accounted for at all times.

Discussion: Applicants shall develop, document, and implement specific procedures as part of a radiation protection program (e.g., operating and emergency procedures) based on sound radiation protection principles to achieve occupational doses and doses to members of the public that are ALARA. These procedures must be specific to the type and form of the licensed material used.

Sealed sources and radiopharmaceuticals used for therapy can deliver significant doses in a short time. 10 CFR 20.1601, 10 CFR 20.1602, 10 CFR 20.1801, and 10 CFR 20.1802 describe access control to high and very high radiation areas and the security of licensed material. Unauthorized access to licensed material by untrained individuals could lead to a significant radiological hazard. Therefore, operating procedures will also need to address access control. Many licensees achieve access control by permitting only trained individuals to have access to licensed material (e.g., keys, lock combinations, security badges). Accountability of licensed material may be ensured by conducting physical inventories, controlling receipt and disposal, and maintaining use records.

If a therapy patient undergoes emergency surgery or dies, it is necessary to ensure the safety of others attending the patient. As long as the patient's body remains unopened, the radiation received by anyone near it is due almost entirely to gamma rays. The change in emphasis when an operation or autopsy is to be performed is due to the possible exposure of the hands and face to relatively intense beta radiation. Procedures for emergency surgery or autopsy can be found in Section 5.3 of NCRP Report No. 37, "Precautions In The Management of Patients Who Have Received Therapeutic Amounts of Radionuclides." Appendix N also provides model procedures for responding to emergency surgery or death of the therapy patient.

Applicants must develop emergency procedures that address a spectrum of incidents (e.g., major spills, leaking source, medical events, interlock failure, stuck source, etc.).

After its occurrence becomes known to the licensee, NRC must be notified when licensed material in excess of 10 times the quantity specified in Appendix C to Part 20 is lost or stolen. The RSO must be proactive in evaluating whether NRC notification is required for any incident involving licensed material. Refer to the regulations (10 CFR 20.2201-20.2203, 10 CFR 30.50, 10 CFR 21.21, 10 CFR 35.3045, 10 CFR 35.3047, and 10 CFR 35.3067) for a description of when notifications are required.

Response from Applicant: No response is necessary. Refer to the subsequent sections for guidance.

Reference: Copies of NCRP Report No. 37, "Precautions In The Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," may be obtained from the National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Suite 800, Bethesda, MD 20814-3095, or ordered electronically at <http://www.ncrp.com>.

8.27 ITEM 10: MATERIAL RECEIPT AND ACCOUNTABILITY

Regulations: 10 CFR 20.1801; 10 CFR 20.1802; 10 CFR 20.1906; 10 CFR 20.2201; 10 CFR 30.34(e); 10 CFR 30.35(g)(2); 10 CFR 30.41; 10 CFR 30.51; 10 CFR 35.27; 10 CFR 35.67.

Criteria: To maintain accountability of licensed material, licensees must do the following:

- Secure licensed material;
- Maintain records of receipt, transfer, and disposal of licensed material;
- Conduct physical inventories at required frequencies to account for licensed material.

Discussion: As Figure 8.14 illustrates, licensed materials must be tracked from "cradle to grave" to ensure accountability, identify when licensed material could be lost, stolen, or misplaced, and ensure that possession limits listed on the license are not exceeded. Licensees exercise control over licensed material accountability by including the following items (as applicable) in their radiation protection program:

- Physical inventories of sealed sources at intervals not to exceed 6 months;
- Ordering and receiving licensed material;
- Package opening;
- Use records.

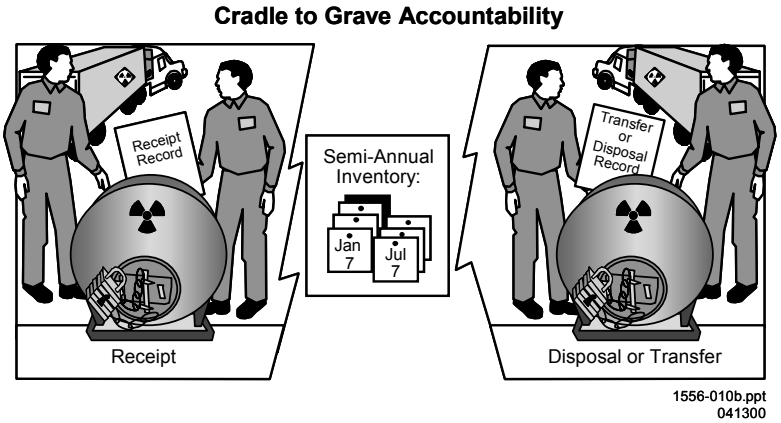

Figure 8.14 Material Receipt and Accountability. *Licensees must maintain records of receipt, transfer, and disposal of licensed material and conduct semiannual physical inventories of sealed sources.*

Response from Applicant: No response is necessary. Refer to the subsequent sections for guidance.

8.28 ITEM 10: ORDERING AND RECEIVING

Regulations: 10 CFR 20.1801; 10 CFR 20.1802; 10 CFR 20.1906; 10 CFR 30.34(e); 10 CFR 30.51.

Criteria: 10 CFR 20.1906 contains the requirements for receiving packages containing licensed material. Additionally, the security of licensed material, required by 10 CFR 20.1801 and 10 CFR 20.1802, must be considered for all receiving areas. 10 CFR 30.51 requires licensees, in part, to maintain records showing the receipt of byproduct material.

Discussion: Licensees must ensure that the type and quantity of licensed material possessed is in accordance with the license. Additionally, licensees must ensure that packages are secured and radiation exposure from packages is minimized.

Appendix O contains model procedures for ordering and receiving licensed material.

Response from Applicant: No response is necessary.

8.29 ITEM 10: OPENING PACKAGES

Regulations: 10 CFR 20.1906; 10 CFR 20.2103; 10 CFR 35.27.

Criteria: Licensees must ensure that packages are opened safely and that the requirements of 10 CFR 20.1906 are met. Licensees must retain records of package surveys in accordance with 10 CFR 20.2103.

Discussion: Licensees must establish, maintain, and retain written procedures for safely opening packages to ensure that the monitoring requirements of 10 CFR 20.1906 are met and that radiation exposure to personnel coming near or in contact with the packages containing radioactive material are ALARA. Appendix P contains model procedures. Applicants are reminded that 10 CFR 20.1906(b) requires, in part, that licensees monitor the external surfaces of a labeled package for radioactive contamination within 3 hours of receipt if it is received during normal working hours, or not later than 3 hours from the beginning of the next working day, if it is received after working hours.

Response from Applicant: Provide the following:

A statement that: "We have developed and will implement and maintain written package opening procedures that meet the requirements of 10 CFR 20.1906."

8.30 ITEM 10: SEALED SOURCE INVENTORY

Regulations: 10 CFR 20.1801; 10 CFR 20.1802; 10 CFR 30.51; 10 CFR 35.67; 10 CFR 35.406; 10 CFR 35.2067; 10 CFR 35.2406.

Criteria: NRC requires the licensee in possession of a sealed source or brachytherapy source to conduct a semi-annual physical inventory of all such sources in its possession. Inventory records must be maintained for 3 years.

Discussion: According to 10 CFR 35.67, the licensee must conduct a semi-annual physical inventory of all sealed sources and brachytherapy sources in its possession. Individual GSR sources are exempt from this physical inventory requirement, as stated in 10 CFR 35.67(g). However, the licensee must maintain records of GSR source receipt, transfer, and disposal, under 10 CFR 30.51, to indicate the current inventory of sources at the licensee's facility. The licensee

shall retain each inventory record in accordance with 10 CFR 35.2067. In addition, 10 CFR 35.406 and 10 CFR 35.2406 require the licensee to make a record of brachytherapy source accountability when removing and returning brachytherapy sources from the storage location.

Response from Applicant: No response is necessary.

8.31 ITEM 10: USE RECORDS

Regulations: 10 CFR 30.51; 10 CFR 35.2063; 10 CFR 35.2204; 10 CFR 35.2406.

Criteria: Licensees must record the use of licensed material to reflect proper use and accountability. Records of use must be maintained for 3 years.

Discussion: Licensees are required to make and maintain records of each dosage activity prior to medical use. The records must include:

- Radiopharmaceutical;
- Patient's or human research subject's name or identification number (if one has been assigned);
- Prescribed dosage, determined dosage, or a notation that the total activity is less than 1.1 MBq (30 μCi);
- Date and time of dosage determination;
- Name of the individual who determined the dosage.

Dosage determination for unit dosages may be made either by direct measurement or by a decay correction based on the determination (e.g., measurement) made by the manufacturer or preparer licensed under 10 CFR 32.72 or equivalent Agreement State requirements.

If molybdenum concentration is measured under 10 CFR 35.204, records of molybdenum concentration must be made and must include:

- Ratio of the measurements expressed as kBq (μCi) of molybdenum-99 per MBq (mCi) of technetium-99m;
- Date and time of the measurement;
- Name of the individual who made the measurement.

If the licensee uses manual brachytherapy sources, the following records of use must be made:

- When temporary implant brachytherapy sources are removed from storage, a record will include the number and activity of sources removed, the time and date they were removed from storage, the location of use, and the name of the individual who removed them from storage.
- When temporary implant brachytherapy sources are returned to storage, a record will include the number and activity of sources returned, the time and date they were returned to storage, and the name of the individual who returned them to storage.
- For permanent implants, a record will be made and will include the number and activity of sources removed from storage, the date they were removed from storage, the name of the individual who removed them from storage, the number and activity of sources not implanted, the date they were returned to storage, the name of the individual who returned them to storage, and the number and activity of sources permanently implanted in the patient or human research subject.

Additionally, to ensure accountability, the licensee should verify that the number of brachytherapy sources before and after the implant are equal. For permanent implants, this means that the total before the implant equals the number of sources implanted plus the number of sources returned or not used.

Response from Applicant: No response is necessary.

8.32 ITEM 10: LEAK TESTS

Regulations: 10 CFR 20.1501; 10 CFR 20.2103; 10 CFR 30.53; 10 CFR 35.67; 10 CFR 35.2067; 10 CFR 35.3067.

Criteria: NRC requires testing to determine if there is any radioactive leakage from sealed sources. Records of test results must be maintained for 3 years.

Discussion: Licensees must perform leak testing of any sealed source or brachytherapy source in accordance with 10 CFR 35.67. Appendix Q provides model leak testing procedures. 10 CFR 35.67 requires licensees to perform leak tests at six-month intervals or at other intervals approved by NRC or an Agreement State and specified in the SSDR certificate and before first use unless accompanied by a certificate indicating that the test was performed within the past 6 months. The measurement of the leak test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 Bq (0.005 μCi) of

radioactivity on the sample. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking (see Figure 8.15).

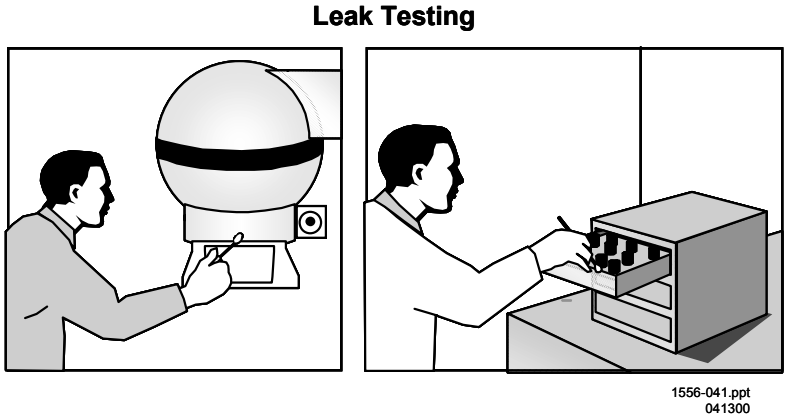

Figure 8.15 Leak Test Sample.

The leak test may be performed in-house or by a contractor who is authorized by NRC or an Agreement State to perform leak tests as a service to other licensees.

The licensee or contractor does not need to leak-test sources if:

- Sources contain only byproduct material with a half-life of less than 30 days;
- Sources contain only byproduct material as a gas;
- Sources contain 3.7 MBq (100 μCi) or less of beta-emitting or gamma-emitting material, or 0.37 MBq (10 μCi) or less of alpha-emitting material;
- Sources contain Ir-192 seeds in nylon ribbon;
- Sources are stored and not being used. The licensee, shall, however, test each such source for leakage before any use or transfer unless it has been leak-tested within 6 months before the date of use or transfer.

Response from Applicant: No response is necessary.

References: See the Notice of Availability on the inside front cover of this report to obtain a copy of NUREG-1556, Vol. 18, "Program-Specific Guidance About Service Provider Licenses," dated November 2000.

8.33 ITEM 10: AREA SURVEYS

Regulations: 10 CFR 20.1003; 10 CFR 20.1101; 10 CFR 20.1201; 10 CFR 20.1301; 10 CFR 20.1302; 10 CFR 20.1501; 10 CFR 20.1801; 10 CFR 20.1802; 10 CFR 20.2102; 10 CFR 0.2103; 10 CFR 20.2107; 10 CFR 35.27; 10 CFR 35.70; 10 CFR 35.2070.

Criteria: Licensees are required to make surveys of potential radiological hazards in their workplace. For example, licensees must perform surveys to:

- Ensure that licensed material will be used, transported, and stored in such a way that members of the public will not receive more than 1 mSv (100 mrem) in 1 year and that the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any 1 hour from licensed operations;
- Ensure that licensed material will be used, transported, and stored in such a way that occupational doses to individuals will not exceed the limits specified in 10 CFR 20.1201;
- Control and maintain constant surveillance over licensed material that is not in storage and secure licensed material from unauthorized access or removal.

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with 10 CFR 20.1101 must include provisions for area surveys. Surveys are evaluations of radiological conditions and potential hazards (see Figure 8.16). These evaluations may be measurements (e.g., radiation levels measured with survey instrument or results of wipe tests for contamination), calculations, or a combination of measurements and calculations. The selection and proper use of appropriate instruments is one of the most important factors in ensuring that surveys accurately assess radiological conditions. To meet regulatory requirements for surveying, measurements of radioactivity should be understood in terms of its properties (i.e. alpha, beta, gamma) and compared to the appropriate limits.

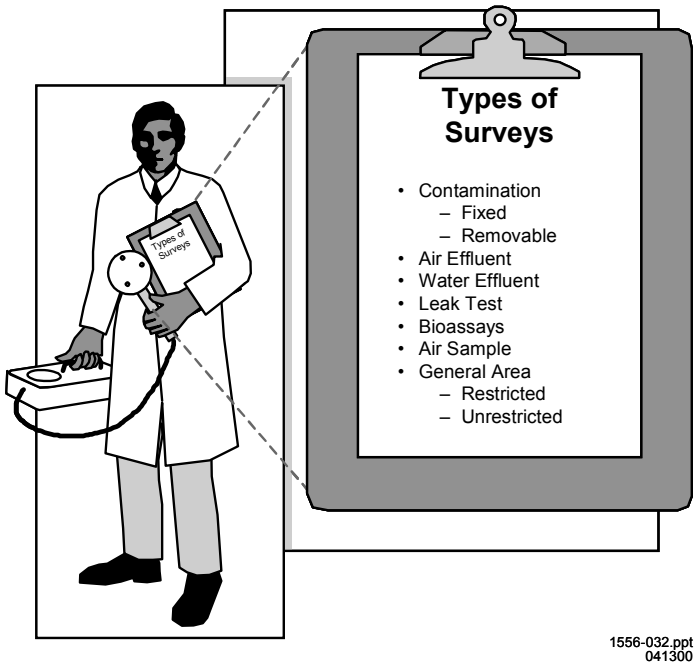

Figure 8.16 Types of Surveys. *There are many different types of surveys performed by licensees.*

Radiation surveys are used to detect and evaluate contamination of:

- Facilities (restricted and unrestricted areas);
- Equipment;
- Incoming and outgoing radioactive packages;
- Personnel (during use, transfer, or disposal of licensed material) (See Figure 8.17).

Licensees also use surveys to plan work in areas where licensed material or radiation exists and to evaluate doses to workers and individual members of the public.

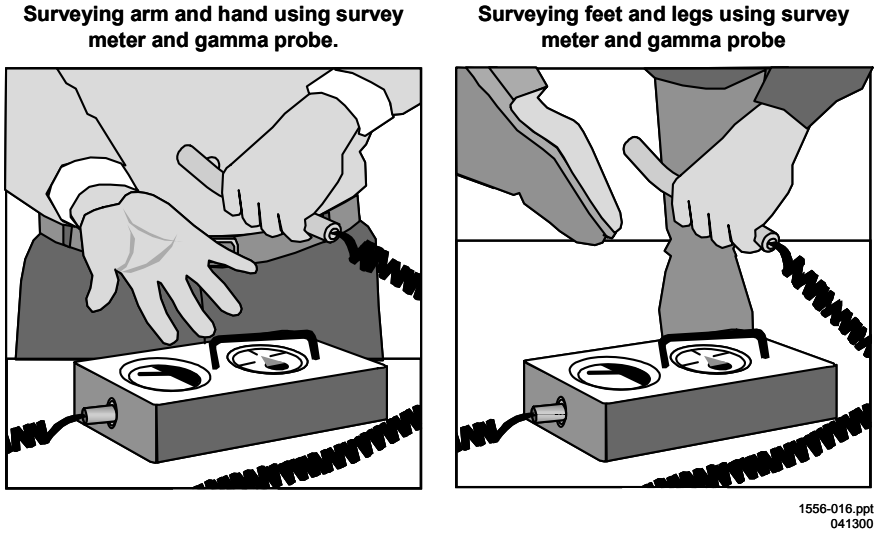

Figure 8.17 Personnel Surveys. *Users of unsealed licensed material should check themselves for contamination (frisk) before leaving the restricted area.*

Surveys are required when it is reasonable under the circumstances to evaluate a radiological hazard and when necessary for the licensee to comply with the appropriate regulations. Licensees may need to perform many different types of surveys due to the particular use of licensed materials. The most important types of surveys are as follows:

- Surveys for radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment;
- Measurements of radioactive material concentrations in air for areas where radiopharmaceuticals are handled or processed in unsealed form and where operations could expose workers to the inhalation of radioactive material (e.g., radioiodine) or where licensed material is or could be released to unrestricted areas;
- Bioassays to determine the kinds, quantities, or concentrations, and in some cases, the location of radioactive material in the human body. Radioiodine uptake in a worker's thyroid gland is commonly measured by external counting using a specialized thyroid detection probe;
- Surveys of external radiation exposure levels in both restricted and unrestricted areas;
- Surveys of radiopharmaceutical packages entering (e.g., from suppliers) and departing (e.g., returned radiopharmaceuticals to the supplier).

The frequency of routine surveys depends on the nature, quantity, and use of radioactive materials, as well as the specific protective facilities, equipment, and procedures that are designed to protect workers and the public from external and internal exposure. Also, the frequency of the survey depends on the type of survey. Appendix R contains model procedures

with suggested survey frequencies for ambient radiation level and contamination surveys. For instance, licensees must perform daily surveys in all areas where radiopharmaceuticals requiring a WD were prepared for use or administered (i.e., diagnostic activities exceeding 30 μCi of I-131 and all therapy treatments); when the licensee administers radiopharamaceuticals requiring a WD in a patient's room, the licensee is not required to perform a survey if the patient is not released. However, the licensee should perform adequate surveys of patients' rooms after patient release and prior to release of the room for unrestricted use.

In addition, therapy sealed sources (including applicators and catheters) may become dislodged during implantation or after surgery, and inadvertently lost or removed. When developing area survey procedures, the licensee should consider surveys of:

- The therapy patient's bed linens before removing them from the patient's room;
- The operating room and the patient's room after source implantation (e.g., radiation level and/or visual check); and
- All trash exiting the patient's room.

The licensee must also perform surveys to ensure that radiation levels around a patient's room after source implantation are within the regulatory requirements [e.g., less than 0.02 mSv (2 mrem) in any 1 hour in any unrestricted area].

Not all instruments can measure a given type of radiation (e.g., alpha, beta, and gamma). The presence of other radiation may interfere with a detector's ability to measure the radiation of interest. The energy of the radiation may not be high enough to penetrate some detector windows and be counted. The correct selection, calibration, and use of radiation detection instruments are important aspects of any radiation safety program. Additionally, applicants are reminded that probe movement speeds and surface-to-probe distances greatly affect ambient exposure rate survey results.

Response from Applicant: Provide the following:

A statement that: "We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70."

8.34 ITEM 10: PROCEDURES FOR ADMINISTRATIONS REQUIRING A WRITTEN DIRECTIVE

Regulations: 10 CFR 35.27; 10 CFR 35.40; 10 CFR 35.41; 10 CFR 35.2040; 10 CFR 35.2041.

Criteria: 10 CFR 35.40 sets forth the requirements for WDs. 10 CFR 35.41 requires medical use licensees to develop, maintain, and implement written procedures to provide high confidence that licensed material is administered as directed by authorized users.

Discussion: The procedures do not need to be submitted to NRC. This gives licensees the flexibility to revise the procedures to enhance effectiveness without obtaining NRC approval. Appendix S provides guidance on developing the procedures.

Response from Applicant: Provide the following:

A statement that: "We have developed and will implement and maintain written procedures for administrations requiring a written directive in accordance with 10 CFR 35.41."

8.35 ITEM 10: SAFE USE OF UNSEALED LICENSED MATERIAL

Regulations: 10 CFR 20.1101; 10 CFR 20.1301; 10 CFR 20.1302; 10 CFR 20.2102; 10 CFR 20.2103; 10 CFR 30.33(a)(2); 10 CFR 30.34(e); 10 CFR 35.27; 10 CFR 35.69; 10 CFR 35.70; 10 CFR 35.310.

Criteria: Before using licensed material, the licensee must develop and implement a radiation protection program that includes safe use of unsealed licensed material.

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with 10 CFR 20.1101 must include provisions for safe use of licensed material. Licensees are responsible for developing, documenting, and implementing procedures to ensure the security and safe use of all licensed material from the time it arrives at their facilities until it is used, transferred, and/or disposed. The written procedures should provide reasonable assurance that only appropriately trained personnel will handle and use licensed material without undue hazard to themselves, other workers, or members of the public.

Users of licensed material must perform surveys required by 10 CFR 20.1302(a) (i.e., surveys of radiation levels and release of effluents to unrestricted and controlled areas). In addition, applicants must constrain doses from air emissions in accordance with 10 CFR 20.1101(d). Records of the results of the measurements are required by 10 CFR 20.2103(b)(4).

Applicants must show how releases to the environment will be ALARA. The general guideline is 10% of the limit specified in 10 CFR 20.1301(a)(1). Licensees that possess sufficient quantities of volatile or potentially volatile licensed material to exceed 10 CFR Part 20 air emissions limits should demonstrate a basis for compliance with the applicable requirements. Such a basis could include one or more of the following:

- Measured concentrations of radionuclides in air effluents are below the concentrations specified in 10 CFR Part 20, Appendix B, Table 2 (and external dose <50 mrem/yr);
- Bounding calculations show that air effluents could not exceed the concentrations specified in 10 CFR Part 20, Appendix B, Table 2 (and external dose <50 mrem/yr);
- Dose modeling shows that the dose equivalent to the individual likely to receive the highest dose does not exceed 10 mrem/yr.

In addition, licensees must develop, implement, and maintain procedures for protective measures to be taken by occupational workers to maintain their doses ALARA. Protective measures may include:

- Use of syringe shields and/or vial shields;
- Wearing laboratory coats and gloves when handling unsealed byproduct material;
- Monitoring hands after handling unsealed byproduct material.

Appendix T contains model procedures for safe use of unsealed licensed material.

Response from Applicant: Provide the following:

A statement that: "We have developed and will implement and maintain procedures for safe use of unsealed licensed material that meet the requirements of 10 CFR 20.1101, 10 CFR 20.1301, and 10 CFR 35.69."

8.36 ITEM 10: INSTALLATION, MAINTENANCE, ADJUSTMENT, REPAIR, AND INSPECTION OF THERAPY DEVICES CONTAINING SEALED SOURCES

Regulations: 10 CFR 20.1101; 10 CFR 30.32; 10 CFR 30.34; 10 CFR 35.605; 10 CFR 35.655; 10 CFR 35.2605; 10 CFR 35.2655.

Criteria: In accordance with 10 CFR 35.605 and 10 CFR 35.655, licensees must ensure that therapy devices containing sealed sources are installed, maintained, adjusted, repaired, and inspected by persons specifically licensed to conduct these activities. The above activities should be conducted according to the manufacturers' written recommendations and instructions and according to the SSDR. In addition, 10 CFR 35.655 requires that teletherapy and GSR units be fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to ensure that the source exposure mechanism functions properly. Maintenance is necessary to ensure that the device functions as designed and source integrity is not compromised.

Discussion: Maintenance and repair includes installation, replacement, and relocation or removal of the sealed source(s) or therapy unit that contains a sealed source(s). Maintenance and repair also includes any adjustment involving any mechanism on the therapy device, treatment console, or interlocks that could expose the source(s), reduce the shielding around the source(s), affect the source drive controls, or compromise the radiation safety of the unit or the source(s).

NRC requires that maintenance and repair (as defined above) be performed only by persons specifically licensed by NRC or an Agreement State to perform such services. Most licensee employees do not perform maintenance and repair because they do not have the specialized equipment and technical expertise to perform these activities. Applicants requesting authorization to possess and use LDR remote afterloaders should review 10 CFR 35.605 before responding to this item. 10 CFR 35.605 allows for an AMP to perform certain service activities with regard to LDR remote afterloader units.

Response from Applicant: No response is necessary if the licensee contracts with personnel who are licensed by NRC or an Agreement State to install, maintain, adjust, repair, and inspect the specific therapy device possessed by the licensee. However, if the applicant requests that an employee who is trained by the manufacturer be authorized to perform the aforementioned activities, the applicant must submit the following:

- Name of the proposed employee and types of activities requested;

AND

- Description of the training and experience demonstrating that the proposed employee is qualified by training and experience for the use requested;

AND

- Copy of the manufacturer's training certification and an outline of the training.

Note: The applicant should specify only those installation, maintenance, inspection, adjustment, and repair functions described in a certificate or letter from the manufacturer of the device that documents the employee's training in the requested function(s).

8.37 ITEM 10: SPILL PROCEDURES

Regulations: 10 CFR 19.11(a)(3); 10 CFR 20.1101; 10 CFR 20.1406; 10 CFR 20.2102; 10 CFR 20.2202; 10 CFR 20.2203; 10 CFR 30.34(e); 10 CFR 30.35(g); 10 CFR 30.50; 10 CFR 30.51; 10 CFR 35.27.

Criteria: Before using licensed material, the licensee must develop, document, and implement a radiation protection program that includes proper response to spills of licensed material.

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with 10 CFR 20.1101 must include provisions for responding to spills or other contamination events in order to prevent the spread of radioactive material. Appendix N contains model emergency response procedures, including model spill procedures. Spill procedures should address all types and forms of licensed material used and should be posted in restricted areas where licensed materials are used or stored. The instructions should specifically state the names and telephone numbers of persons to be notified (e.g., RSO, staff, state and local authorities, and NRC, when applicable). Additionally, the instructions should contain procedures for evacuation of the area, containment of spills and other releases, appropriate methods for reentering, and for decontaminating facilities (when necessary).

Response from Applicant: Provide the following:

A statement that: "We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.1101."

8.38 ITEM 10: EMERGENCY RESPONSE FOR SEALED SOURCES OR DEVICES CONTAINING SEALED SOURCES

Regulations: 10 CFR 19.11(a)(3); 10 CFR 20.1101; 10 CFR 20.2102; 10 CFR 20.2201-2203; 10 CFR 21.21; 10 CFR 21.51; 10 CFR 30.34(e); 10 CFR 30.50; 10 CFR 30.51; 10 CFR 35.27; 10 CFR 35.410; 10 CFR 35.610; 10 CFR 35.2310; 10 CFR 35.2610.

Criteria: Before handling sealed sources or using devices containing sealed sources, the applicant must develop, document, and implement written procedures for emergency response. For instance, 10 CFR 35.610 requires, in part, that written procedures be developed, implemented, and maintained for responding to an abnormal situation involving a remote afterloader unit, a teletherapy unit, or a gamma stereotactic radiosurgery unit. The procedures must include:

- Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;
- The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and
- The names and telephone numbers of AUs, AMPs, and the RSO to be contacted if the unit or console operates abnormally.

A copy of these procedures must be physically located at the therapy unit console. The instructions must inform the operator of procedures to be followed if the operator is unable to place the source(s) in the shielded position, or remove the patient from the radiation field with controls from outside the treatment room.

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with 10 CFR 20.1101 must include provisions for responding to incidents involving sealed sources or devices containing sealed sources. Appendix N contains model emergency response procedures for teletherapy units. Emergency procedures must address all types of licensed material and devices used and should be posted in restricted areas where sealed sources are used or stored. The instructions must specifically state the names and telephone numbers of persons to be notified, e.g., RSO, staff, state and local authorities, and NRC, when applicable. Additionally, the instructions must contain procedures for evacuation and security of the involved area(s), source recovery, area reentry, and decontamination of facilities (if applicable). All equipment necessary for complying with emergency procedures shall be available near each treatment room; for example, these may include remote handling tools, t-bars, Allen keys, and shielded containers.

The applicant must establish and follow written procedures for emergencies that may occur (e.g., a manual brachytherapy source becomes dislodged, a therapy source fails to retract or return to the shielded position, or a GSR couch fails to retract). A copy of the manufacturer's recommendations and instructions should be given to each individual performing therapy treatments or operating the therapy device. Practice drills, using nonradioactive (dummy) sources (when possible), must be practiced annually or more frequently, as needed. The drills should include dry runs of emergency procedures that cover stuck or dislodged sources and applicators (if applicable), and emergency procedures for removing the patient from the radiation field. Team practice may also be important for adequate emergency coordination for such maneuvers as removing a patient from a malfunctioning GSR unit and manual movement of the patient treatment table. These procedures, designed to minimize radiation exposure to patients, workers, and the general public should, at a minimum, address the following points, as applicable to the type of medical use:

- When the procedures are to be implemented, such as any circumstance in which the source becomes dislodged, cannot be retracted to a fully shielded position, or the patient cannot be removed from the beam of radiation.
- The actions specified for emergency source recovery or shielding that primarily consider minimizing exposure to the patient and health care personnel while maximizing safety of the patient.
- The step-by-step actions for single or multiple failures that specify the individual(s) responsible for implementing the actions. The procedures should clearly specify which steps are to be taken under different scenarios. The procedure should specify situations in which surgical intervention may be necessary and the steps that should be taken in that event.
- Location of emergency source recovery equipment and specification of what equipment may be necessary for various scenarios. At a minimum, emergency equipment should include shielded storage containers, remote handling tools, and if appropriate, supplies necessary to surgically remove applicators or sources from the patient and tools necessary for removal of the patient from the device.
- Giving first consideration to minimizing exposure to the patient, usually by removing the patient from the room (rather than using tools to attempt to return the source to the off position). ***Note:*** If the first step of the emergency procedures for teletherapy units specifies pressing the emergency bar on the teletherapy unit console, the applicant is advised that this action may cause the source to return to the off position but may also cut power to the entire teletherapy unit or to the gantry or the couch.
- Instructing the staff to act quickly and calmly, and to avoid the primary beam of radiation.
- Specifying who is to be notified.

- Requirements to restrict (lock, as necessary) and post the treatment area with appropriate warning signs as soon as the patient and staff are out of the treatment room.

Response from Applicant: Provide the following:

- A statement that: "We have developed and will implement and maintain written procedures for safe response to emergencies involving sealed sources in accordance with 10 CFR 20.1101 and 10 CFR 35.12 that meet the requirements in 10 CFR 35.410 and 10 CFR 35.610, as applicable."

AND

- Procedures developed in accordance with 10 CFR 35.610(a)(4).

8.39 ITEM 10: PATIENT OR HUMAN RESEARCH SUBJECT RELEASE

Regulations: 10 CFR 35.27; 10 CFR 35.75; 10 CFR 35.2075.

Criteria: Licensees may release from confinement patients or human research subjects (patients) who have been administered licensed material if the TEDE to any other individual from exposure to the released patient is not likely to exceed 5 mSv (0.5 rem). Licensees must provide radiation safety instructions to patients released (or their parent or guardian) in accordance with 10 CFR 35.75(b).

Discussion: 10 CFR 35.75 requires that the licensee provide the released individual (patient) with instructions, including written instructions, on actions recommended to maintain doses to other individuals ALARA if the TEDE to any other individual is likely to exceed 1 mSv (0.1 rem). If the dose to a breast-feeding infant or a child could exceed 1 mSv (0.1 rem), assuming there was no interruption of breast-feeding, the instructions also shall include:

- Guidance on the interruption or discontinuation of breast-feeding; and
- Information on the potential consequences of failure to follow the guidance. This implies that the licensee will confirm whether a patient is breast-feeding before releasing the patient.

In addition, 10 CFR 35.75(c) and 10 CFR 35.2075 require that the licensee maintain a record of the basis for authorizing the release of an individual for 3 years after the release date, if the TEDE is calculated by:

- Using the retained activity rather than the activity administered;
- Using an occupancy factor less than 0.25 at 1 meter;
- Using the biological or effective half-life; or
- Considering the shielding by tissue.

In 10 CFR 35.75(d) and 10 CFR 35.2075, the licensee is required to maintain a record for 3 years after the date of release that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a TEDE exceeding 5 mSv (0.5 rem).

Appendix U provides guidance to the applicant for determining when:

- The licensee may authorize the release of a patient who has been administered radiopharmaceuticals or who has been treated with implants containing radioactive material (Section 1);
- Instructions to the patient are required by 10 CFR 35.75(b) (Section 2);
- Records are required by 10 CFR 35.75(c) and (d) and 35.2075 to be generated and maintained (Section 3).

The appendix lists activities for commonly used radionuclides and the corresponding dose rates with which a patient may be released in compliance with the dose limits in 10 CFR 35.75.

Response from Applicant: Provide the following:

A statement that: "We have developed and will provide written instructions to patients or human research subjects (or their parent or guardian) released under 10 CFR 35.75 that meet the requirements in 10 CFR 35.75."

8.40 ITEM 10: SAFETY PROCEDURES FOR TREATMENTS WHERE PATIENTS ARE HOSPITALIZED

Regulations: 10 CFR 20.1101; 10 CFR 20.1501; 10 CFR 20.1801; 10 CFR 20.2103; 10 CFR 35.315; 10 CFR 35.404; 10 CFR 35.604; 10 CFR 35.415; 10 CFR 35.615; 10 CFR 35.2404.

Criteria: Applicants must develop and implement procedures to ensure that access to therapy treatment rooms, and exposure rates from therapy treatments, are limited to maintain doses to occupational workers and members of the public ALARA.

Discussion: 10 CFR 35.315, 10 CFR 35.415, and 10 CFR 35.615 require the licensee to take certain safety precautions regarding radiopharmaceutical therapy, manual brachytherapy, or remote afterloader brachytherapy involving patients hospitalized in accordance with 10 CFR 35.75. This section does not include teletherapy or GSR outpatient treatments. The precautions are to ensure compliance with the exposure limits in 10 CFR Part 20.

10 CFR 35.404(b) and 10 CFR 35.604(a) require licensees to perform a radiation survey of the patient (and the remote afterloader unit) immediately after removing the last temporary implant source from the patient and prior to releasing the patient from licensee control. This is done to confirm that all sources have been removed and accounted for. A record of the patient survey must be maintained for 3 years. 10 CFR 35.615(e) requires that when sources are placed within the patient's body, licensed activities be limited to treatments that allow for expeditious removal of a decoupled or jammed source.

In addition, applicants must take the following steps:

- Provide a private room with a private sanitary facility for patients treated with a radiopharmaceutical therapy dosage (Note: 10 CFR 35.315(a) allows for a room shared with another radiopharmaceutical therapy patient);
- Provide a private room for patients implanted with brachytherapy sources (***Note:*** 10 CFR 35.415 allows for a room shared with another brachytherapy patient);
- Visibly post a "Radioactive Materials" sign on the patient's door and note on the door or in the patient's chart where and how long visitors may stay in the patient's room (10 CFR 35.315 and 10 CFR 35.415);
- Either monitor material and items removed from the patient's room (e.g., patient linens, surgical dressings, etc.) with a radiation detection survey instrument set on its most sensitive scale with no interposed shielding to determine that their radioactivity cannot be distinguished from the natural background radiation level or to confirm that they do not contain brachytherapy sources, or handle them as radioactive waste (10 CFR 35.315 and 10 CFR 20.1501);
- Notify the RSO, or his/her designee, and AU as soon as possible if the patient has a medical emergency or dies (10 CFR 35.315, 10 CFR 35.415, and 10 CFR 35.615).

10 CFR 20.1501 requires licensees to perform adequate surveys to evaluate the extent of radiation levels. Therefore, licensees must evaluate the exposure rates around patients who are

hospitalized in accordance with 10 CFR 35.75 following the dosage administration or implant (e.g., measured exposure rates, combination of measured and calculated exposure rates).

10 CFR 20.1801 requires licensees to secure licensed material in storage from unauthorized access or removal. Therefore, licensees must ensure that access to rooms where patients are hospitalized, in accordance with 10 CFR 35.75, is limited to authorized personnel. Access control and appropriate training of authorized personnel may prevent unauthorized removal of licensed material and unnecessary personnel exposures.

In order to control exposures to individuals in accordance with 10 CFR Part 20, the licensee should consider briefing patients on radiation safety procedures for confinement to bed, visitor control, identification of potential problems, notification of medical staff in the event of problems, and other items as applicable and consistent with good medical care.

Response from Applicant: No response is necessary.

8.41 ITEM 10: PROCEDURES FOR DEVICE CALIBRATION, SAFETY CHECKS, OPERATION, AND INSPECTION

Regulations: 10 CFR 20.1101; 10 CFR 20.1301; 10 CFR 20.1501; 10 CFR 20.2102; 10 CFR 20.2103; 10 CFR 20.2107; 10 CFR 30.34(e); 10 CFR 35.27; 10 CFR 35.604; 10 CFR 35.605; 10 CFR 35.610; 10 CFR 35.615; 10 CFR 35.632; 10 CFR 35.633; 10 CFR 35.635; 10 CFR 35.642; 10 CFR 35.643; 10 CFR 35.645; 10 CFR 35.652; 10 CFR 35.655; 10 CFR 35.657; 10 CFR 35.2310; 10 CFR 35.2404; 10 CFR 35.2605; 10 CFR 35.2610; 10 CFR 35.2632; 10 CFR 35.2642; 10 CFR 35.2643; 10 CFR 35.2645; 10 CFR 35.2652; 10 CFR 35.2655.

Criteria: Applicants must develop, maintain, and implement procedures for providing radiation safety for the use of sealed sources in devices. Applicants must also develop, maintain, and implement procedures to ensure that therapy sources and devices are calibrated and operating correctly.

Pertinent information in equipment manuals and other publications may be extracted and included in operating procedures, as applicable. Applicable AAPM documents may be referenced. A list of references is provided at the end of this section and may be helpful to applicants in providing responses in this area.

Discussion: Each functional area of medical use of sealed sources in devices is discussed separately below. The applicant should review the functional area(s) that apply to the type of

medical use requested. Operating procedures shall be sufficient to ensure compliance with NRC regulations.

Diagnostic Sealed Sources and Devices

NRC regulations and good health physics practice require the licensee to provide personnel with clear and specific instructions on the medical use of sealed sources and devices. The SSDR for the specific source and device and the sealed source manufacturer's "device-specific" literature and instructions may help licensees develop the required instructions. These procedures may include, but are not limited to:

- Service and repair of the device;
- Routine proper use for sealed sources or devices containing sealed sources in accordance with the NRC license and 10 CFR Parts 19, 20, and 35;
- Description of checks performed on the device to verify its proper operation after it has been moved and before it is used on patients, including the manufacturer's instruction for start-up, warm-up time, and phantom analysis for bone mineral analyzers;
- Safety and security measures.

Teletherapy, Remote Afterloader, and GSR Sealed Sources and Devices

NRC regulations and good health physics practice require the licensee to provide personnel (e.g., medical physicists, technologists, and authorized users) with clear and specific instructions on the medical use of sealed sources and devices. Instructions should be tailored to the duties and responsibilities of the individual receiving instruction, whose duties may include safety device checks, instrument calibration, periodic spot checks, quality control checks, and leak tests. For example, housekeeping personnel who have access to therapy treatment rooms for cleaning would not follow the same instructions as therapy technologists operating therapy machines for patient treatment. Nursing personnel involved with remote afterloader treatments should receive specific instructions regarding a patient's care during the treatment process, especially if the treatment is to be conducted over a period of several hours and direct patient care is required. Applicants shall develop, maintain, and implement procedures to ensure that access to therapy treatment rooms and exposure rates from therapy treatments are limited to maintain doses to occupational workers and members of the public ALARA. The applicant must develop, maintain, and implement written procedures governing the operation of the therapy unit. The procedures must include:

- Use of the therapy unit, including security of the device, the console, and the console keys;
- Surveys of the therapy unit and remote afterloader patients;
- Computer system acceptance testing;
- Safety device checks;
- Periodic spot check measurements;
- Inspection and servicing;
- Full calibration measurements;
- Relocation of unit;
- Recordkeeping.

The functional areas listed above are described in more detail below.

Use of the Therapy Unit

The operating procedures described in 10 CFR 35.610(d)(2) should specify who may operate the unit, how the unit may be used (i.e., in what orientations, for what purposes), typical treatment times and setups, how the unit is to be operated (i.e., the sequence of steps to be followed to begin treatment), and who must be present during the treatment. For example, the AU and AMP must be present for all GSR treatments. In addition, the licensee is reminded of the following requirements and may want to include descriptions of acceptable practice in the written procedures:

- Under 10 CFR 35.610(a)(2), a licensee must ensure that only individuals approved by the AU, RSO, or AMP are present (e.g., the patient) in the treatment room during treatment with the source(s).
- Under 10 CFR 35.615(e), if a source(s) is to be placed within the patient, a treatment procedure shall not be conducted if a decoupled or jammed source cannot be removed expeditiously from the patient.
- Under 10 CFR 35.642(e), 10 CFR 35.643(e), and 10 CFR 35.645(f), if the interlock system malfunctions, the device will be locked in the off position and not used, except as may be necessary for repair, replacement, or check of the interlock system, until the interlock system is shown to be functioning properly.
- Under 10 CFR 35.642(e), 10 CFR 35.643(e), and 10 CFR 35.645(f), if a source exposure indicator light on the unit, control console, or facility is found to be either inoperable or intermittently inoperable, the device will be locked in the off position and not used, except as

may be necessary for repair, replacement, or check of the indicator light until the indicator light is shown to be functioning properly.

- Under 10 CFR 35.610(a)(1), the licensee shall secure the unit, the console, the console keys, and the treatment room when not in use or unattended.

Surveys of the Therapy Unit

In accordance with 10 CFR 35.652, surveys following source replacement or repairs to the unit that could compromise the radiation safety of the unit or the source(s) in devices must be conducted. At a minimum, the survey program must include surveys defined in the SSDR to ensure that the maximum and average radiation levels from the surface of the device source safe do not exceed the levels stated in the SSDR with the source(s) in the shielded position. The licensee should develop procedures to address these surveys and any additional surveys that may be required by 10 CFR 20.1501 to assess potential radiological hazards (e.g., the device location changes significantly since the previous survey or as part of a response to a device alarm to ensure that the source(s) has been returned to the fully shielded position).

Safety Device Checks

Safety devices shall be checked periodically to ensure that they are operating properly. The frequency required by the regulations for each safety device varies. Such devices include timers, mechanical and electrical interlocks, warning lights and alarms, helmet position indicator microswitches, safety switches, door interlocks, beam collimators, and other devices that actively limit radiation exposure to patients and actively warn of, limit, or prevent radiation exposure to personnel. The results shall be recorded. The operating procedures shall contain instructions for making the checks, the frequency of such checks, prompt correction of any malfunctions or defects noted, and retention of appropriate records. A simple checklist may be used to complete the task and recordkeeping quickly and efficiently.

10 CFR 35.12(b)(2) requires an applicant to submit procedures required for therapy device spot checks developed in accordance with 10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645.

When checks of safety devices indicate defects or malfunctions, there may be some delay before the defects or malfunctions can be corrected. The operating procedures should describe the steps that personnel will follow if a delay occurs. For example, using the therapy unit might be prohibited until the problem is corrected.

Documents such as ANSI N449.1-1978, “Procedures for Periodic Inspection of Cobalt-60 and Cesium-137 Teletherapy Equipment,” NCRP Report 69, “Dosimetry of X-Ray and Gamma-Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV,” NUREG/CR-6323, “Relative Risk Analysis in Regulating the Use of Radiation-Emitting Medical Devices,”

NUREG/CR-6324, "Quality Assurance for Gamma Knives," and AAPM Report No. 54, "Stereotactic Radiosurgery," provide standards and recommendations for the frequency and procedures for making certain tests. If the standards or recommendations in these documents conflict with NRC regulations or license conditions, the minimum acceptable frequency is that specified in the regulation or license condition.

Relocation of Therapy Unit

10 CFR 35.13 requires that NRC approve a proposed location *before* a therapy unit is relocated (i.e., adds to or changes the areas of use identified in the application or on the license). The operating procedures should ensure that the necessary amendment to the NRC license is obtained before the therapy unit is relocated.

Inspection and Servicing of the Therapy Unit

10 CFR 35.655 requires that teletherapy and GSR units be fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first. This work, to assure proper functioning of the source exposure mechanism, must be done by a person or firm licensed to do so by NRC or an Agreement State. Preventive maintenance should also be addressed in the operating procedures to ensure that as systems deteriorate from use, they are identified and repaired. The operating procedures should include the following as related to the GSR: hydraulic system maintenance; collimator helmet supports, holes, plugs, bushings, and other helmet positioning equipment; and the systems related to the patient couch and the shielding door. Persons holding an Agreement State license are granted a general license to perform the same activities in non-Agreement States, pursuant to the requirements of 10 CFR 150.20. In addition, 10 CFR 35.605 limits device installation, maintenance, adjustment, and repair to certain designated personnel. The licensee should review the regulations in this section to ensure that compliance is achieved.

Computer System Acceptance Testing

10 CFR 35.657 requires that a licensee perform acceptance testing on the computerized treatment planning system that includes verification of the items listed in 10 CFR 35.657(a) through (e). Such acceptance testing must be performed in accordance with published protocols accepted by nationally recognized bodies (e.g., ANSI).

Periodic Spot Check Measurements of Teletherapy Units

10 CFR 35.642 specifies that output spot check tests must be performed once in each calendar month, and 10 CFR 35.630 describes the characteristics of a properly calibrated dosimetry system needed to make the output measurements. 10 CFR 35.642 also describes additional

safety spot checks of each facility and the unit that must be performed monthly and at each source installation. The operating procedures must specify when and how the output spot check measurements will be made and should specify by whom the spot check tests will be made. The output measurements required shall be performed in accordance with procedures established by an AMP. The AMP need not actually perform the output spot check measurements; however, the AMP must review the results of each output spot check within 15 days and notify the licensee as soon as possible, in writing, of the results of each spot check, as required by 10 CFR 35.642(c).

Teletherapy Full Calibration Measurements

10 CFR 35.632 requires that a licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy source before the first medical use of the unit and under the conditions listed in 10 CFR 35.632(a)(2) and (a)(3). The full calibration measurements must be performed in accordance with published protocols accepted by nationally recognized bodies (e.g., ANSI).

Periodic Spot Check Measurements of GSR Units

10 CFR 35.645 specifies that output spot check tests must be performed once in each calendar month, and 10 CFR 35.630 describes the characteristics of a properly calibrated dosimetry system needed to make the output measurements. 10 CFR 35.645 also describes additional safety spot checks of each facility and the unit that must be performed monthly, prior to first use on a given day, and after each source exchange. The operating procedures must specify when and how the spot check measurements will be made and should specify by whom the spot check tests will be made. The measurements shall be performed in accordance with procedures established by an AMP. The AMP need not actually perform the spot check measurements; however, the AMP must review the results of each spot check within 15 days and notify the licensee as soon as possible, in writing, of the results of each spot check, as required by 10 CFR 35.645(b)(2).

GSR Full Calibration Measurements

10 CFR 35.635 requires that a licensee authorized to use a GSR unit for medical use shall perform full calibration measurements on each GSR source before the first medical use of the unit and under the conditions listed in 10 CFR 35.635(a)(2) and (a)(3). Such full calibration measurements must be performed in accordance with published protocols accepted by nationally recognized bodies (e.g., ANSI).

Surveys of Remote Afterloader Patients

In accordance with 10 CFR 35.604, the licensee must perform surveys incident to use, including patient surveys performed after each treatment with a remote afterloader source. The patient must be surveyed with a portable radiation detection survey instrument to confirm that the source(s) has been removed and returned to the safe shielded position. The survey instrument should be capable of measuring dose rates of 1 - 1000 mrem per hour at a distance of 1 meter.

Periodic Spot Check Measurements of Remote Afterloader Units

10 CFR 35.643 specifies that spot check tests must be performed after each source installation and prior to the first use on a given day for all types of remote afterloaders, except low dose-rate remote afterloaders. Spot check tests on low dose-rate remote afterloaders must be performed after each source installation and before each patient treatment. The operating procedures must specify when and how the spot check measurements will be made and should specify by whom the spot check tests will be made. The measurements shall be performed in accordance with procedures established by an AMP. The AMP need not actually perform the spot check measurements; however, the AMP must review the results of each spot check measurement within 15 days and notify the licensee as soon as possible, in writing, of the results of each spot check, as required by 10 CFR 35.643(c).

Remote Afterloader Full Calibration Measurements

10 CFR 35.633 requires that a licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit before the first medical use of the unit and under the conditions listed in 10 CFR 35.633(a)(2), (a)(3), and (a)(4). Such full calibration measurements must be performed in accordance with published protocols accepted by nationally recognized bodies (e.g., ANSI).

Recordkeeping

The licensee must maintain certain records to comply with NRC regulations, the conditions of the license, and commitments made in the license application and correspondence with NRC. Operating procedures should identify which individuals in the organization are responsible for maintaining which records. Examples of documents that must be maintained include:

- Copies of NRC licenses, license applications, and correspondence with NRC in support of a license request (10 CFR 19.11);
- Personnel dosimetry records (10 CFR 20.2103);

- Records of survey instrument calibrations (10 CFR 20.2103, 10 CFR 35.61, and 10 CFR 35.2061);
- Records of calibration of the dosimetry system used for full calibration measurements (10 CFR 35.630 and 10 CFR 35.2630);
- Records of calibration or intercomparison of the dosimetry system used for spot check measurements (10 CFR 35.630 and 10 CFR 35.2630);
- Results of full calibration measurements (10 CFR 35.632, 10 CFR 35.633, 10 CFR 35.635 and 10 CFR 35.2632);
- Results of spot check measurements (10 CFR 35.642, 10 CFR 35.643, 10 CFR 35.645, 10 CFR 35.2642, 10 CFR 35.2643, and 10 CFR 35.2645);
- Results of leak tests (10 CFR 35.67 and 10 CFR 35.2067);
- Records of instruction of new personnel and annual refresher training of personnel (10 CFR 35.610 and 10 CFR 35.2610);
- Records of instruction in emergency procedures (10 CFR 35.610 and 10 CFR 35.2610);
- Records of full inspection and servicing of the therapy unit (10 CFR 35.605, 10 CFR 35.655, 10 CFR 35.2605, and 10 CFR 35.2655);
- Records of receipt and disposal of radioactive material (10 CFR 30.51).

Response from Applicant: Provide the following:

- A statement that: "We have developed and will implement and maintain written procedures for safe medical use of sealed sources and devices and calibration of sources in accordance with 10 CFR 20.1101 and 10 CFR 35.12 that meet the requirements of the applicable section(s) of 10 CFR Part 35, Subparts G and H."

AND

- Procedures developed in accordance with 10 CFR 35.610, 10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645, as applicable.

References: Copies of ANSI N449.1-1978, "Procedures for Periodic Inspection of Cobalt-60 and Cesium-137 Teletherapy Equipment," may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018, or ordered electronically from <http://www.ansi.org>. Copies of NCRP Report 69, "Dosimetry of X-Ray and Gamma-Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV," may be obtained from the National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Suite 800, Bethesda, MD 20814-3095, or ordered electronically from <http://www.ncrp.com>.

See the Notice of Availability on the inside front cover of this report to obtain copies of NUREG/CR-6323, "Relative Risk Analysis in Regulating the Use of Radiation-Emitting Medical Devices," NUREG/CR-6276, "Quality Management in Remote Afterloading Brachytherapy," and NUREG/CR-6324, "Quality Assurance for Gamma Knives." Copies of AAPM Report No. 54, "Stereotactic Radiosurgery," may be obtained from the American Association of Physicists in Medicine, One Physics Ellipse, College Park, MD 20740-3843, or ordered electronically from <http://www.aapm.org>.

8.42 ITEM 10: MOBILE MEDICAL SERVICE

Regulations: 10 CFR 20.1101; 10 CFR 30.41; 10 CFR 30.51; 10 CFR 35.2; 10 CFR 35.18; 10 CFR 35.80; 10 CFR 35.647; 10 CFR 35.2080; 10 CFR 35.2647; 10 CFR 71.5; 10 CFR 71.12; 10 CFR 71.13; 10 CFR 71.14; 10 CFR 71.37; 10 CFR 71.38; Subpart H of 10 CFR Part 71; 10 CFR 150.20; 49 CFR Parts 171-178.

Criteria: In addition to the requirements in 10 CFR 35.80, mobile medical service licensees must comply with all other applicable regulations.

Discussion: Appendix V describes specific licensing items pertaining to mobile services. "Temporary job site" means a location, other than specific location(s) of use authorized on the license, where mobile medical services are conducted. Mobile medical service licensees may transport licensed material and equipment into a client's building, or may bring patients into the transport (e.g., van). In either case, the van should be located on the client's property that is under the client's control. Additionally, in-van imaging services may not be considered an NRC-licensed activity if services are limited to patient imaging (i.e., byproduct material is not administered), and byproduct material is not possessed or used.

Self-contained mobile service involves a mobile treatment or administration facility that provides ready-to-deliver mobile services on arrival at a client's site. The facility is entirely self-contained with a shielded treatment or administration area, remote afterloader device (if applicable), and safety equipment (e.g., dose calibrators, patient viewing systems, intercom, etc.).

Transportable mobile service involves transport of the byproduct material for use in a pre-existing shielded treatment or administration facility at the client site. The mobile service licensee may provide the byproduct material, associated equipment, and trained personnel, or the client may choose to provide the trained personnel to use the byproduct material. Before using a remote afterloader for this type of service, the device must be installed in an appropriately shielded treatment room. Other support equipment, such as viewing systems, area monitors, and intercoms must have been separately installed and available for use in the treatment room before treatment of patients commences.

To facilitate the licensing of mobile medical services, the types of services provided are broken down into the following 3 classes:

- Class 1 mobile service providers (byproduct material, trained personnel, and facility) are authorized to provide the device/facility (e.g., in-van use) and treatment of (or administration to) patients at the client site. Class 1 mobile service providers are responsible for all aspects of byproduct material use and authorized patient treatments (or administrations).
- Class 2 mobile service providers (byproduct material and trained personnel) are authorized to provide the transportation to and use of the byproduct material within the client's facility. Class 2 mobile service providers are also responsible for all aspects of byproduct material use and authorized patient treatments (or administrations).
- Class 3 mobile service providers (byproduct material only) are authorized to provide the byproduct material to a client site so that the client can perform treatments (or administrations). Under this class of service, the mobile service provider authorization is limited to the possession, limited servicing, and transport of the byproduct material and associated equipment. The client will need a separate authorization (license) to perform patient treatments (or administrations) with the byproduct material and the client will be responsible for all aspects of byproduct material use and patient treatment(s) (or administrations), as applicable, including, but not limited to, dose calibrator measurements, sealed source calibration, remote afterloader device function checks, and all safety system checks.

A mobile service provider may apply for one or multiple classes of service. However, a single client site may be authorized only for a single class of service. This restriction on client sites is intended to eliminate possible confusion that may arise over responsibilities for use and control of byproduct materials at client sites authorized for multiple classes of service.

Class 1 and Class 2 mobile medical service licensees must ensure that patients treated meet the release criteria in 10 CFR 35.75.

Note: Agreement State licensees that request reciprocity for activities conducted in non-Agreement States are subject to the general license provisions described in 10 CFR 150.20. This general license authorizes persons holding a specific license from an Agreement State to conduct the same activity in non-Agreement States if the specific license issued by the Agreement State does not limit the authorized activity to specific locations or installations. NRC licensees who wish to conduct operations at temporary job sites in an Agreement State should contact that state's Radiation Control Program Office for information about state regulations, including notification requirements, and to determine if mobile medical services are allowed within the Agreement State through reciprocity. Therefore, to ensure compliance with Agreement State reciprocity requirements, an NRC licensee shall request authorization well in advance of

scheduled work. In addition to the requirements specified in 10 CFR 150.20, applicants requesting a mobile service license should contact all states where they plan to conduct mobile services, to clarify requirements associated with an authorization to practice medicine within the state's jurisdiction.

Response from Applicant: Refer to Appendix V for the type of additional information to provide.

8.43 ITEM 10: TRANSPORTATION

Regulations: 10 CFR 20.1101; 10 CFR 30.41; 10 CFR 30.51; 10 CFR 71.5; 10 CFR 71.9; 10 CFR 71.12; 10 CFR 71.13; 10 CFR 71.14; 10 CFR 71.37; 10 CFR 71.38; Subpart H of 10 CFR Part 71; 49 CFR Parts 171-178.

Criteria: Applicants who will prepare for shipment, ship, or transport radioactive materials, including radioactive waste, must develop, implement, and maintain safety programs for the transport of radioactive material to ensure compliance with NRC and DOT regulations.

Discussion: Most packages of licensed material for medical use contain quantities of radioactive material that require use of Type A packages. Additionally, many packages shipped by medical licensees (e.g., unused radiopharmaceutical dosages) frequently meet the "Limited Quantity" criteria described in 49 CFR 173.421 and are therefore excepted from certain DOT requirements, provided certain other less restrictive requirements are met [e.g., activity in the package is less than the limited quantity and the radiation level on the surface of the package does not exceed 0.005 mSv per hour (0.5 mrem per hour)].

The general license in 10 CFR 71.12, "General license: NRC-approved package," provides the authorization used by most licensees to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, certificate of compliance, or other approval has been issued by NRC. This general license is subject to certain conditions. 10 CFR 71.5 sets forth the requirements for transportation of licensed material. 10 CFR 71.9 exempts any physician licensed by a state to dispense drugs in the practice of medicine, who is also licensed under 10 CFR Part 35 or the equivalent Agreement State regulations from the requirements in 10 CFR 71.5. This exemption applies to transport by the physician of licensed material for use in the practice of medicine.

Some medical use licensees (e.g., teletherapy or gamma stereotactic radiosurgery) may need to ship licensed material in Type B packages. 10 CFR 71.12-71.14 sets forth the Type B package requirements for transporting or delivering the package to a carrier for transport. These include registration as a user of the package and having an NRC-approved quality assurance (QA) plan.

For information about these QA plans, see Revision 1 of RG 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," dated June 1986. For further information about registering as a user of a package or submitting a QA program for review, contact NRC's Spent Fuel Project Office by calling NRC toll-free at (800) 368-5642, extension 415-8500. For information about associated fees, contact NRC's OCFO by calling NRC toll-free at (800) 368-5642, extension 415-7544.

Some medical use licensees that ship radioactive material have chosen to transfer possession of radioactive materials to a manufacturer (or service licensee) with an NRC or Agreement State license, who then acts as the shipper. The manufacturer (or service licensee), who is subject to the provisions of 10 CFR 71.12 or 10 CFR 71.14, as appropriate, then becomes responsible for proper packaging of the radioactive materials and compliance with NRC and DOT regulations. Licensees who do this must ensure that the manufacturer (or service licensee):

- Is authorized to possess the licensed material at temporary job sites (e.g., the licensee's facilities);
- Actually takes possession of the licensed material under its license.

Additionally, for Type B package shipments, the licensee should verify and the manufacturer (or service licensee) must:

- Use an approved Type B package;
- Register with NRC as a user of the Type B package;
- Possess an NRC-approved QA plan.

For each shipment, it must be clear who possesses the licensed material and who is responsible for proper packaging of the radioactive materials and compliance with NRC and DOT regulations.

During an inspection, NRC uses the provisions of 10 CFR 71.5 and a Memorandum of Understanding with DOT on the Transportation of Radioactive Material (signed June 6, 1979) to examine and enforce various DOT requirements applicable to medical use licensees. Appendix W lists major DOT regulations that apply to medical licensees.

Response from Applicant: No response is needed from applicants during the licensing phase. However, before making shipments of licensed materials on its own in a Type B package, a licensee must have registered with NRC as a user of the package and obtained NRC's approval of its QA program. Transportation issues will be reviewed during inspection.

References: "A Review of Department of Transportation Regulations for Transportation of Radioactive Materials" can be obtained be calling DOT's Office of Hazardous Material Initiatives and Training at (202) 366-4425. See the Notice of Availability on the inside front cover of this report to obtain a copy of the Memorandum of Understanding with DOT on the Transportation of Radioactive Material, signed June 6, 1979, and Revision 1 of RG 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," dated June 1986.

8.44 ITEM 11: WASTE MANAGEMENT

Regulations: 10 CFR 20.1101; 10 CFR 20.1301; 10 CFR 20.1501; 10 CFR 20.1904; 10 CFR 20.2001-2007; 10 CFR 20.2102; 10 CFR 20.2103; 10 CFR 20.2107; 10 CFR 20.2108; 10 CFR 30.33(a)(2); 10 CFR 30.41; 10 CFR 30.51; 10 CFR 31.11; 10 CFR 35.27; 10 CFR 35.92; 10 CFR 35.2092; 10 CFR 61.3; 10 CFR 71.5.

Criteria: Licensed materials must be disposed of in accordance with NRC requirements by:

- Transfer to an authorized recipient;
- Decay-in-storage (DIS);
- Release in effluents within the limits in 10 CFR 20.1301; or
- As authorized under 10 CFR 20.2002 through 20.2005.

Appropriate records must be maintained.

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with 10 CFR 20.1101 must include provisions for waste disposal of licensed material. Appendix X contains model procedures for DIS and generator or other licensed material return. 10 CFR 20.2001 requires that licensees dispose of licensed material only by means specified therein. In 10 CFR 20.2006, NRC requires that for licensed material transferred to a land disposal facility, the licensee must comply with the specific requirements in 10 CFR 20.2006 and Appendix G to 10 CFR Part 20, i.e., manifest, certification, and control and tracking. 10 CFR 35.92 specifies the requirements for handling of waste by DIS. In accordance with 10 CFR 71.5, NRC requires that licensees who transport licensed material outside the site of usage, or where transport is on public highways, or who deliver it for transport, comply with the applicable regulations of DOT in 49 CFR Parts 170 through 189. Applicants are reminded to take into account the following information when they develop procedures (as applicable):

- Except for material suitable for DIS and some animal carcasses handled by the licensee, solids are transferred to an authorized recipient licensed to receive such waste in accordance with 10 CFR 20.2001(b), 10 CFR 20.2006, or in applicable regulations in 10 CFR Parts 30 or 61. Follow the packaging instructions received from the transfer agent and the burial site operator. Keep the consignment sheet from the transfer agent as the record of disposal.
- When setting up a program for DIS, consider short-term and long-term storage. Long-term storage should be designed to allow for segregation of wastes with different half-lives (e.g., the use of multiple shielded containers). Containers should have shielded covers to maintain occupational exposure at ALARA levels. Storage areas must be in a secure location.
- Waste from *in vitro* kits (except mock iodine-125) that are generally licensed under 10 CFR 31.11 is exempt from waste disposal regulations in 10 CFR Part 20, as set forth in 10 CFR 31.11(f). Radioactive labels should be defaced or removed. There is no need to keep any record of release or make any measurement.
- Consider the monitoring and control mechanisms in place to ensure compliance with the appropriate requirements regarding the release of material into air and water under 10 CFR 20.1302 and 20.2003, respectively.
  - — Regulations for disposal in the sanitary sewer appear in 10 CFR 20.2003. Material must be readily soluble or dispersible in the water. There are also monthly and annual limits, based on the total sanitary sewerage release of the facility. (Excreta from patients undergoing medical diagnosis or therapy are not subject to these limitations; see 10 CFR 20.2003(b)). Make a record of the disposal in accordance with 10 CFR 20.2108.
  - — Limits on permissible concentrations in effluents to unrestricted areas are enumerated in Table II of Appendix B to 10 CFR Part 20. These limits apply at the boundary of the restricted area. Make a record of the release in accordance with 10 CFR 20.2103 and 10 CFR 20.2107.
  - — Liquid scintillation-counting media containing 1.85 kBq (0.05 μCi) per gram of H-3 or C-14 may be disposed of without regard to its radioactivity (10 CFR 20.2005(a)(1)). Make a record of the disposal in accordance with 10 CFR 20.2108.
- If applicants/licensees propose to treat or dispose of licensed material by incineration, they must receive specific approval from NRC. Contact the appropriate NRC Regional Office for guidance on treatment or disposal of material by incineration in accordance with 10 CFR 20.2004.
- Applicants that wish to use waste volume reduction operations (e.g., compactors) must provide a detailed description (as outlined below), along with their response to Item 8.16 (Facility Diagram):

— A description of the compactor to demonstrate that it is designed to safely compact the waste generated (e.g., manufacturer's specifications, annotated sketches, photographs);

— The types, quantities, and concentrations of the waste to be compacted;

— An analysis of the potential for airborne release of radioactive material during compaction activities;

— The location of the compactors in the waste processing area(s), as well as a description of the ventilation and filtering systems used in conjunction with the compactors, and procedures for monitoring filter blockage and exchange;

— Methods used to monitor worker breathing zones and/or exhaust systems;

— The types and frequencies of surveys that will be performed for contamination control in the compactor area;

— The instructions provided to compactor operators, including instructions for protective clothing, checks for proper functioning of equipment, method of handling uncompacted waste, and examining containers for defects.

General Guidance for Waste Disposal

- Under 10 CFR 20.1904 and 10 CFR 35.92, all radioactivity labels must be removed or obliterated from empty or adequately decayed containers and packages prior to disposal in in-house (non-radioactive) waste. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed. If waste is decayed biomedical waste, labels may not need to be defaced. In accordance with 10 CFR 35.92(a)(2), radiation labels do not require removal or obliteration if the label is on materials that are within containers that will be managed as biomedical waste after they have been released from the licensee.
- Remind employees that non-radioactive waste such as leftover reagents, boxes, and packing material should not be mixed with radioactive waste.
- Occasionally monitor all procedures to ensure that radioactive waste is not created unnecessarily. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.
- In all cases, consider the impact of various available disposal routes, including occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability), and expense.

DIS

For radionuclides of byproduct material with a half-life of less than 120 days, licensees may dispose of waste in ordinary trash as long as the following criteria are followed:

- Hold byproduct material for decay until the waste cannot be distinguished from background level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding;
- Remove or obliterate all radiation labels, except as noted above;
- Maintain proper records.

Returning Sources

Because of the nature of the material contained in brachytherapy, teletherapy, and GSR sources, the only option for disposal is transfer to an authorized recipient as specified in 10 CFR 20.2001(a)(1). Authorized recipients are the original manufacturer of the sealed source, a commercial firm licensed by NRC or an Agreement State to accept radioactive waste from other persons, or another specific licensee authorized to possess the licensed material (i.e., their license specifically authorizes possession of the same radionuclide, form, and use).

Medical licensees are often the first to come into contact with plutonium-powered pacemakers or the first to be contacted by nursing homes and funeral homes when a patient implanted with a pacemaker dies. If the pacemaker was not originally implanted by your facility, you should contact the hospital where the pacemaker was implanted to arrange for explantation and notify NRC. The licensee (e.g., the implanting hospital) is responsible for the follow-up, explantation, and return of the pacemaker to the manufacturer for proper disposal. NRC Information Notice 98-12, "Licensees' Responsibilities Regarding Reporting and Follow-up Requirements for Nuclear-Powered Pacemakers," provides additional information.

Before transferring radioactive material, a licensee must verify that the recipient is authorized to receive the material using one of the methods described in 10 CFR 30.41. Additionally, 10 CFR 71.5 requires that licensees who transport licensed material outside the site of usage, or where transport is on public highways, or who deliver it to a carrier for transport, comply with the regulations of DOT in 49 CFR Parts 170 through 189. Records of the transfer must be maintained as required by 10 CFR 30.51.

Licensees should promptly dispose of unused sealed sources to minimize potential problems such as access by unauthorized individuals, use for inappropriate purposes, and improper disposal.

Because of the difficulties and costs associated with disposal of sealed sources, applicants should preplan the disposal. Applicants may want to consider contractual arrangements with the source supplier as part of a purchase agreement.

Licensees are cautioned that, on several occasions, incinerator and sanitary landfill operators have returned waste shipments that have triggered their portal monitors. Information Notice 99-33, "Management of Wastes Contaminated with Radioactive Materials," describes this issue in greater detail. In many cases, the waste is from patients who have been released under 10 CFR 35.75. Licensees should review state and local ordinances for disposal of waste at these facilities to ensure that their waste is acceptable.

Response from Applicant: Provide the following:

A statement that: "We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of Subpart K to 10 CFR Part 20 and 10 CFR 35.92."

The next two items on NRC Form 313 are to be completed on the form itself.

8.45 ITEM 12: FEES

Regulations: 10 CFR 170.31.

On NRC Form 313, enter the appropriate fee category from 10 CFR 170.31 and the amount of the fee enclosed with the application.

8.46 ITEM 13: CERTIFICATION

Individuals acting in a private capacity are required to date and sign NRC Form 313. Otherwise, representatives of the corporation or legal entity filing the application should date and sign NRC Form 313. These representatives must be authorized to make binding commitments and to sign official documents on behalf of the applicant. An application for licensing a medical facility must be signed by the applicant's or licensee's management. The individual who signs the application should be identified by title of the office held. As discussed previously in "Management Responsibility," signing the application acknowledges management's commitment and responsibilities for the radiation protection program. NRC will return all unsigned applications for proper signature.

Notes:

- It is a criminal offense to make a willful false statement or representation on applications or correspondence (18 U.S.C. 1001).
- When the application references commitments, they become part of the licensing conditions and regulatory requirements.

9 AMENDMENTS AND RENEWALS TO A LICENSE

Regulations: 10 CFR 2.109; 10 CFR 30.34; 10 CFR 30.36(a); 10 CFR 30.38; 10 CFR 35.13; 10 CFR 35.14.

It is the licensee's obligation to keep the license current. 10 CFR 30.34 describes the terms and conditions of licenses. If any of the information provided in the original application is to be modified or changed by the licensee, the licensee may submit an application for a license amendment, as described in 10 CFR 30.38 and 10 CFR 35.13, to reflect the proposed change. Because 10 CFR 30.34 requires that the licensee follow the terms and conditions of the license, the licensee must receive authorization for the change before the change takes place, except for those items outlined in 10 CFR 35.14. Also, to continue a license after its expiration date, the licensee must submit an application for a license renewal at least 30 days before the expiration date (10 CFR 2.109, 10 CFR 30.36(a)).

10 CFR 35.13 requires a licensee to apply for and receive a license amendment before several activities can occur, including:

- Receipt or use of byproduct material for a type of use permitted by Part 35, but not authorized on the licensee's current Part 35 license;
- Permitting anyone to work as an AU, AMP, or ANP, unless the individual meets one of the exceptions listed in 10 CFR 35.13(b);
- Changing the RSO;
- Receiving byproduct material in excess of the amount, or receiving radionuclides or forms different than currently authorized on the NRC license;
- Changing an area or address of use identified in the application or on the license, except for areas of use where byproduct material is used only in accordance with either 10 CFR 35.100 or 10 CFR 35.200.

For renewal and amendment requests, applicants should do the following:

- Use the most recent guidance in preparing an amendment or renewal request;
- Submit in duplicate either an NRC Form 313 or a letter requesting an amendment or renewal;
- Provide the license number;

- For license renewals, provide a complete and up-to-date application if many outdated documents are referenced, or if there have been significant changes in regulatory requirements, NRC's guidance, the licensee's organization, or the radiation protection program; alternatively, describe clearly the exact nature of the changes, additions, and deletions;

Note: Using the wording of responses suggested in this report will expedite NRC's review.

10 TERMINATION OF ACTIVITIES

Regulation: 10 CFR 20.1401-1405; 10 CFR 30.6; 10 CFR 30.34(b); 10 CFR 30.35(g); 10 CFR 30.36; 10 CFR 30.51.

Criteria: The licensee must do the following:

- Notify NRC, in writing, within 60 days, when its license has expired or a decision has been made to permanently cease licensed activities at the entire site, regardless of contamination levels;
- Notify NRC, in writing, within 60 days, when principal activities have not been conducted for 24 months or a decision has been made to permanently cease licensed activities in any separate building or outdoor area, if those areas contain residual radioactivity making them unsuitable for release according to NRC requirements;
- Certify the disposition of licensed materials by submitting NRC Form 314, "Certificate of Disposition of Materials," or equivalent information;
- Before a license is terminated, send the records important to decommissioning (as required by 10 CFR 30.35(g)) to the appropriate NRC Regional Office, or if licensed activities are transferred or assigned according to 10 CFR 30.34(b), transfer records important to decommissioning to the new licensee.

Discussion: Subpart E to 10 CFR Part 20 describes the radiological criteria for license termination. A licensee's determination that a facility is not contaminated is subject to verification by NRC inspection.

Licensees may maintain information on surveys and leak tests on an ongoing basis and as a means of providing evidence and assurance of an appropriate decommissioning status upon the termination of licensed activities and/or release of a site for non-licensed use.

NRC Form 314 found in Appendix Y may be used by licensee's for documenting the disposition of their licensed material.

For additional guidance on the disposition of licensed material, see Section 8.44, "Waste Management." For guidance on decommissioning records, see Section 8.6, "Financial Assurance and Recordkeeping for Decommissioning."

Licensees should promptly dispose of unused licensed material to minimize potential problems, such as access by unauthorized individuals, use for inappropriate purposes, or improper disposal.

Response from Applicant: The applicant is not required to submit a response to NRC during the initial application. However, when the license expires or at the time the licensee ceases operations, then the applicant must perform decommissioning activities and submit NRC Form 314 or equivalent information.

Reference: Copies of NRC Form 314, "Certificate of Disposition of Materials," are available upon request from NRC's Regional or Field Offices; see Appendix Y.

Appendix A

List of Documents Considered in Development of this NUREG

List of Documents Considered in Development of this NUREG

This report incorporates and updates the guidance previously found in the Regulatory Guides (RG), Policy and Guidance Directives (P&GD), and Information Notices (IN) listed in the table below. When this report is issued in final form, the documents in the table will be considered superseded and should not be used. Other references were also used in this report and are listed in "References."

Document Identification	Title	Date
RG 10.8, Revision 2	Guide for the Preparation of Applications for Medical Use Programs.	8/87
Appendix X to RG 10.8, Revision 2	Guidance on Complying With New Part 20 Requirements.	6/92
Draft RG DG-0009	Supplement to Regulatory Guide 10.8, Revision 2, Guide for the Preparation of Applications for Medical Use Programs.	3/97
Draft RG FC 414-4	Guide for the Preparation of Applications for Licenses for Medical Teletherapy Programs.	12/85
P&GD FC 87-2	Standard Review Plan (SRP) for License Applications for the Medical Use of Byproduct Material.	12/87
Supplement 1 to P&GD FC 86-4; Revision 1	Mobile Remote Afterloading Brachytherapy Licensing Module.	5/97
P&GD FC 86-4, Revision 1	Information Required for Licensing Remote Afterloading Devices.	9/93
Addendum to Revision 1 to P&GD FC 86-4	Information Required for Licensing Remote Afterloading Devices – Increased Source Possession Limits.	7/95
P&GD 3-15	Standard Review Plan for Review of Quality Management Programs.	6/95
RG 8.39	Release of Patients Administered Radioactive Materials.	4/97
RG 8.33	Quality Management Program.	10/91

Document Identification	Title	Date
P&GD 3-17 (previously 16)	Review of Training and Experience Documentation Submitted by Proposed Physician User Applicants.	
RG 8.23	Radiation Safety Surveys at Medical Institutions, Revision 1.	1/81

The additional references listed below were used.

References

Title 10, Code of Federal Regulations

1. Part 2 – Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders.
2. Part 19 – Notices, Instructions, and Reports to Workers; Inspections and Investigations.
3. Part 20 – Standards for Protection Against Radiation.
4. Part 21 – Reporting of Defects and Noncompliance.
5. Part 30 – Rules of General Applicability to Domestic Licensing of Byproduct Material.
6. Part 31 – General Domestic Licenses for Byproduct Material.
7. Part 32 – Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material.
8. Part 33 – Specific Domestic Licenses of Broad Scope for Byproduct Material.
9. Part 35 – Medical Use of Byproduct Material.
10. Part 40 – Domestic Licensing of Source Material.
11. Part 70 – Domestic Licensing of Special Nuclear Material.
12. Part 71 – Packaging and Transportation of Radioactive Material.
13. Part 150 – Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters Under Section 274.
14. Part 170 – Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, As Amended.
15. Part 171 – Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC.

Title 49, Code of Federal Regulations

1. Part 172 – Hazardous Materials Table, Special Provisions, Hazardous Materials Communications, Emergency Response Information, and Training Requirements.
2. Part 173 – Shippers – General Requirements for Shipments and Packagings.
3. Part 177 – Carriage by Public Highway.
4. Part 178 – Specifications for Packagings.

NRC Regulatory Guides (RG)

1. RG 1.86 – Termination of Operating Licenses for Nuclear Reactors, June 1974.
2. RG 3.66 – Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72, June 1990.
3. RG 7.10, Revision 1 – Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material, June 1986.
4. RG 8.4 – Direct-Reading and Indirect-Reading Pocket Dosimeters, February 1973.
5. RG 8.7 – Instructions for Recording and Reporting Occupational Radiation Exposure Data, Revision 1, June 1992.
6. RG 8.9 – Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program, Revision 1, June 1993.
7. RG 8.10 – Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable, Revision 1-B, September 1975.
8. RG 8.13 (Draft) – Instruction Concerning Prenatal Radiation Exposure, October 1994.
9. RG 8.18 – Information Relevant to Ensuring that Occupational Radiation Exposures at Medical Institutions Will Be As Low As Reasonably Achievable, Revision 1, October 1982.
10. RG 8.20 – Applications of Bioassay for I-125 and I-131, Revision 1, September 1979.
11. RG 8.21 – Health Physics Surveys for Byproduct Material at NRC-Licensed Processing and Manufacturing Plants.
12. RG 8.25 – Air Sampling in the Workplace, Revision 1, June 1992.
13. RG 8.29 – Instruction Concerning Risks from Occupational Radiation Exposure, Revision 1, February 1996.

14. RG 8.34 – Monitoring Criteria and Methods to Calculate Occupational Radiation Doses, July 1992.
15. RG 8.36 – Radiation Dose to the Embryo/Fetus, July 1992.
16. RG 10.2 – Guidance to Academic Institutions Applying for Specific Byproduct Material Licenses of Limited Scope, Revision 1, December 1976.
17. RG 10.5 (Draft) – Applications for Type A Licenses of Broad Scope, October 1994.
18. RG 10.8, 1997 – Revision (Draft NUREG-1569 - never published), Program-Specific Guidance for Medical Use Licensees.
19. RG FC 412-4 (Draft) – Guide for the Preparation of Applications for the Use of Radioactive Materials in Leak-Testing Services, June 1985.
20. RG FC 413-4 (Draft) – Guide for the Preparation of Applications for Licenses for the Use of Radioactive Materials in Calibrating Radiation Survey and Monitoring Instruments, June 1985.

NRC Information Notices (IN)

1. IN 89-25, Revision 1 – Unauthorized Transfer of Ownership or Control of Licensed Activities.
2. IN 94-70 – Issues Associated with Use of Strontium-89 and Other Beta Emitting Radiopharmaceuticals.
3. IN 96-28 – Suggested Guidance Relating to Development and Implementation of Corrective Action.
4. IN 97-30 – Control of Licensed Material During Reorganizations, Employee-Management Disagreements, and Financial Crises.
5. IN 99-33 – Management of Wastes Contaminated with Radioactive Materials.

NRC Policy and Guidance Directives (P&GD)

1. P&GD FC 90-2, Revision 1 – Standard Review Plan for Evaluating Compliance with Decommissioning Requirements, April 1991.
2. P&GD PG 1-23 – Guidance for Multi-Site Licenses, April 1996.

3. P&GD PG 8-11 – NMSS Procedures for Reviewing Declarations of Bankruptcy, August 1996.
4. P&GD FC 92-01 – Information Required for Licensing Mobile Nuclear Medicine Services, April 1992.

NRC NUREGs

1. NUREG-0267, Revision 1 – Principles and Practices for Keeping Occupational Radiation Exposures at Medical Institutions As Low As Reasonably Achievable, October 1982.
2. NUREG-1134 – Radiation Protection Training for Personnel Employed in Medical Facilities, May 1985.
3. NUREG-1492 – Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material, February 1997.
4. NUREG-1516 – Effective Management of Radioactive Materials Safety Programs at Medical Facilities, May 1997.
5. NUREG-1539 – Methodology and Findings of the NRC's Materials Licensing Process Redesign, April 1996.
6. NUREG-1541 (Draft) – Process and Design for Consolidating and Updating Materials Licensing Guidance, April 1996.
7. NUREG-1556, Volume 3 (July 1998) – Consolidated Guidance about Materials Licensees: Applications for Sealed Source and Device Evaluation and Registration, September 1997.
8. NUREG-1600 – General Statement of Policy and Procedures for NRC Enforcement Actions, June 1995 and Compilation of NRC Enforcement Policy as of September 10, 1997.
9. NUREG/CR-4444 – Radiation Safety Issues Related to Radiolabeled Antibodies, 1991.
10. NUREG/CR-4884 – Interpretation of Bioassay Measurement, July 1987.
11. NUREG/CR-6323 – Relative Risk Analysis in Regulating the Use of Radiation-Emitting Medical Devices: A Preliminary Application, September 1995.
12. NUREG/CR-6324 – Quality Assurance for Gamma Knives, September 1995.

National Council on Radiation Protection and Measurements (NCRP) Publications

1. NCRP Report No. 30 – Safe Handling of Radioactive Materials, 1964.
2. NCRP Report No. 37 – Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides, 1970.
3. NCRP Report No. 40 – Protection Against Radiation from Brachytherapy Sources, 1972.
4. NCRP Report No. 49 – Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies up to 10 MeV, 1976.
5. NCRP Report No. 57 – Instrumentation and Monitoring Methods for Radiation Protection, 1978.
6. NCRP Report No. 58 – A Handbook of Radioactivity Measurement Procedures, Second Edition, 1985.
7. NCRP Report No. 69 – Dosimetry of X-Ray and Gamma-Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV, 1981.
8. NCRP Report No. 71 – Operational Radiation Safety – Training, 1983.
9. NCRP Report No. 87 – Use of Bioassay Procedures for Assessment of Internal Radionuclide Deposition, February 1987.
10. NCRP Report No. 102 – Medical X-Ray, Electron Beam and Gamma Ray Protection for Energies up to 50 MeV (Equipment Design, Performance and Use), 1989.
11. NCRP Report No. 105 – Radiation Protection for Medical and Allied Health Personnel, 1989.
12. NCRP Report No. 107 – Implementation of the Principle of As Low As Reasonably Achievable (ALARA) for Medical and Dental Personnel, 1990.
13. NCRP Commentary No. 11 – Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients, February 1995.

International Commission on Radiological Protection (ICRP) Publications

1. ICRP Report No. 26 – Recommendations of the International Commission on Radiological Protection, 1977.
2. ICRP Report No. 30 – Limits for Intakes of Radionuclides by Workers, 1978.
3. ICRP Report No. 35 – General Principles of Monitoring for Radiation Protection of Workers, 1982.

4. ICRP Publication No. 53 – Radiation Dose to Patients from Radiopharmaceuticals, 1987.

5. ICRP Publication 54 – Individual Monitoring for Intake of Radionuclides by Workers: Design and Interpretation, 1987.

ANSI Standards

1. ANSI N13.4-1971 (R1983) – Specification of Portable X- or Gamma Radiation Survey Instruments.

2. ANSI N13.5-1972 (R1989) – Performance and Specifications for Direct Reading and Indirect Reading Pocket Dosimeters for X- and Gamma Radiation.

3. ANSI N13.6-1966 (R1989) – Practice for Occupational Radiation Exposure Records Systems.

4. ANSI N14.5-1987 – Leakage Tests on Packages for Shipment of Radioactive Materials.

5. ANSI N42.12-1994 – Calibration and Usage of Thallium-Activated Sodium Iodide Detector Systems for Assay of Radionuclides.

6. ANSI N42.13-1986 (R1993) – Calibration and Usage of Dose Calibrator Ionization Chambers for the Assay of Radionuclides.

7. ANSI N42.15-1990 – Performance Verification of Liquid Scintillation Counting Systems.

8. ANSI N42.17A-1989 – Performance Specifications for Health Physics Instrumentation-Portable Instrumentation for Use in Normal Environmental Conditions.

9. ANSI N322 – Inspection and Test Specifications for Direct and Indirect Reading Quartz Fiber Pocket Dosimeters.

10. ANSI N323A-1997 – Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments.

11. ANSI N449.1-1978 (R1984) – Procedures for Periodic Inspection of Cobalt-60 and Cesium-137 Teletherapy Equipment.

American Association of Physicists in Medicine (AAPM) Reports

1. AAPM Task Group No. 21 – A Protocol for the Determination of Absorbed Dose from High-Energy Photon and Electron Beams, 1984.

2. AAPM Radiation Therapy Committee Task Group No. 40 – Comprehensive QA for Radiation Oncology, 1994.

3. AAPM Radiation Therapy Committee Task Group No. 56 – Code of Practice for Brachytherapy Physics, 1998.

4. AAPM Radiation Therapy Committee Task Group No. 59 – HDR Treatment Delivery Safety, 1997 Draft.

5. AAPM Report No. 41 – Remote Afterloading Technology, 1993.

6. AAPM Report No. 54 – Stereotactic Radiosurgery, 1995.

Other Technical Publications

1. International Commission on Radiation Units and Measurements (ICRU), "Certification of Standardized Radioactive Sources," Report No. 12, 1968.

2. U.S. Department of Health, Education, and Welfare, "Radiological Health Handbook," 1970.

3. R.C.T. Buchanan and J.M. Brindle, "Radioiodine Therapy to Out-patients – The Contamination Hazard," *British Journal of Radiology*, Volume 43, 1970.

4. International Atomic Energy Agency (IAEA), "Monitoring of Radioactive Contamination on Surfaces," Technical Report Series No. 120, 1970.

5. IAEA, "Handbook on Calibration of Radiation Protection Monitoring Instruments," Technical Report Series No. 133, 1971.

6. A.P. Jacobson, P.A. Plato, and D. Toeroek, "Contamination of the Home Environment by Patients Treated with Iodine-131," *American Journal of Public Health*, Volume 68, Number 3, 1978.

7. A. Brodsky, "Resuspension Factors and Probabilities of Intake of Material in Process (or 'Is 10-6 a Magic Number in Health Physics?')," *Health Physics*, Volume 39, Number 6, 1980.

8. Bureau of Radiological Health, "Radiation Safety in Nuclear Medicine: A Practical Guide," Department of Health and Human Services (HHS) Publication FDA 82-8180, November 1981.

9. Center for Devices and Radiological Health, "Recommendations for Quality Assurance Programs in Nuclear Medicine Facilities," HHS Publication FDA 85-8227, October 1984.

10. S. R. Jones, "Derivation and Validation of a Urinary Excretion Function for Plutonium Applicable over Ten Years Post Intake," *Radiation Protection Dosimetry*, Volume 11, No. 1, 1985.

11. "Guidelines for Patients Receiving Radioiodine Treatment," *Society of Nuclear Medicine*, 1987.

12. J. R. Johnson and D. W. Dunford, "GENMOD – A Program for Internal Dosimetry Calculations," AECL-9434, Chalk River Nuclear Laboratories, Chalk River, Ontario, 1987.

13. K.F. Eckerman, A.B. Wolbarst, and A.C.B. Richardson, "Federal Guidance Report No. 11, Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion," Report No. EPA-520/1-88-020, 1988.

14. K. W. Skrable et al., "Intake Retention Functions and Their Applications to Bioassay and the Estimation of Internal Radiation Doses," *Health Physics Journal*, Volume 55, No. 6, 1988.

15. A.S. Meigooni, S. Sabnis, R. Nath, "Dosimetry of Palladium-103 Brachytherapy Sources for Permanent Implants," *Endocurietherapy Hyperthermia Oncology*, Volume 6, April 1990.

16. R. Nath, A.S. Meigooni, and J.A. Meli, "Dosimetry on Transverse Axes of 125I and 192Ir Interstitial Brachytherapy Sources," *Medical Physics*, Volume 17, Number 6, November/December 1990.

17. M.G. Stabin et al., "Radiation Dosimetry for the Adult Female and Fetus from Iodine-131 Administration in Hyperthyroidism," *Journal of Nuclear Medicine*, Volume 32, Number 5, May 1991.

18. P. Early, D. B. Sodee, "Principles and Practice of Nuclear Medicine," 2nd ed., 1995.

19. M. Stabin, "Internal Dosimetry in Pediatric Nuclear Medicine," *Pediatric Nuclear Medicine*, 1995.

20. "Intravascular Brachytherapy – Guidance for Data to be Submitted to the Food and Drug Administration In Support of Investigational Device Exemption (IDE) Applications," Draft Version 1.3, 1996.

21. R.O. Dunkelberger, II, "Which Probe Should I Use," *Baltimore-Washington Health Physics Society Newsletter.*

Appendix B

NRC Form 313

NRC FORM 313 U. S. NUCLEAR REGULATORY COMMISSION

(8-1999)
10 CFR 30, 32, 33
34, 35, 36, 39 and 40

APPLICATION FOR MATERIAL LICENSE

APPROVED BY OMB: NO. 3150-0120 EXPIRES:08/31/2002

Estimated burden per response to comply with this mandatory information collection request: 7.4 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records Management Branch (T-6 E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to bjs1@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

SAM NUNN ATLANTA FEDERAL CENTER
U. S. NUCLEAR REGULATORY COMMISSION, REGION II
61 FORSYTH STREET, S.W., SUITE 23T85
ATLANTA, GEORGIA 30303-8931

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S.NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*
   - ☐ A. NEW LICENSE
   - ☐ B. AMENDMENT TO LICENSE NUMBER _____
   - ☐ C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip code)*

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

TELEPHONE NUMBER

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
   a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
    FEE CATEGORY | AMOUNT ENCLOSED $

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING 18 U.S.C. SECTION 1001 ACT OFJUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			$		
APPROVED BY				DATE	

Appendix C

License Application Checklist and Sample Licenses

License Application Checklist and Sample Licenses

The instructions in Table C.1, Applicability Table, may be followed to determine if the information must be provided or if "NA" may be the response to each item that follows.

To determine those items to which you must respond, "highlight" the columns under the categories of materials you requested in Item 5. If any "Y" beside an item is highlighted, you must provide detailed information in response to the item. If the letters "NA" (not applicable) are highlighted, you may respond "NA" on your application. If any "N" beside an item is highlighted, no information in response is required, however, the NRC regulations that apply to the given category apply to your type of license. If any "P" beside an item is highlighted, you must provide a commitment to develop, implement, and maintain a procedure in response to the item. Note that some modules have additional item numbers that may need to be addressed. "APP" indicates the applicable appendices found in this document.

In addition, sample licenses are included that may provide guidance on the particular type of medical use you are requesting.

Table C.1 Applicability Table.

Item #	Topic	35.100/200	35.300	35.400	35.500	35.600	35.1000	APP
N/A	Unsealed Byproduct Material – Uptake, Dilution, Excretion, Imaging, and Localization Studies	Y						
N/A	Unsealed Byproduct Material – Written Directive Required		Y					
N/A	Manual Brachytherapy			Y				
N/A	Sealed Sources for Diagnosis				Y			
N/A	Teletherapy Units					Y		
N/A	Remote Afterloader Units					Y		
N/A	Gamma Stereotactic Radiosurgery Units					Y		
N/A	Other Medical Uses (e.g., Emerging Technologies)						Y	
8.6	Financial Assurance Determination	Y	Y	Y	Y	Y	Y	E
8.7	Sealed Source Registry	N	N	Y	Y	Y	Y	
8.10	Radiation Safety Officer	Y	Y	Y	Y	Y	Y	F, G

APPENDIX C

Item #	Topic	35.100/200	35.300	35.400	35.500	35.600	35.1000	APP
8.11	Authorized User(s)	Y	Y	Y	Y	Y	Y	G
8.12	Authorized Nuclear Pharmacist(s)	Y	Y	N/A	N/A	N/A	Y	G
8.13	Authorized Medical Physicist(s)	N/A	N/A	Y	N/A	Y	Y	G
8.14	Training Program	N	N	N	N	N	N	H
8.16	Facility Diagram and Equipment	Y	Y	Y	Y	Y	Y	
8.17	Radiation Monitoring Instrument Calibration	P	P	P	N	P	P	I
8.18	Dose Calibrator Calibration	P	P	N/A	N/A	N/A	P	J
8.19	Dosimetry Equipment and Therapy Sealed Source Calibration	N/A	N/A	P	N/A	P	P	
8.20	Other Equipment and Facilities	Y	Y	Y	Y	Y	Y	
8.22	Audit Program	N	N	N	N	N	N	K
8.23	Occupational Dose	P	P	P	P	P	P	L
8.24	Public Dose	N	N	N	N	N	N	M
8.25	Minimization of Contamination	Y	Y	Y	Y	Y	Y	
8.28	Ordering and Receiving	N	N	N	N	N	N	O
8.29	Opening Packages	P	P	P	P	P	P	P
8.30	Sealed Source Inventory	N	N	N	N	N	N	
8.31	Use Records	N	N	N	N	N	N	
8.32	Leak Tests	N	N	N	N	N	N	Q
8.33	Area Surveys	P	P	P	P	P	P	R
8.34	Written Directive Procedures	N/A	P	P	N/A	P	P	S
8.35	Safe Use of Unsealed Licensed Material	P	P	N/A	N/A	N/A	P	T
8.36	Service of Therapy Devices Containing Sealed Sources	N/A	N/A	N/A	N/A	Y	Y	
8.37	Spill Procedures	P	P	N/A	N/A	N/A	P	N
8.38	Emergency Response for Sealed Sources or Devices	N/A	N/A	P	P	Y	Y	N

Item #	Topic	35.100/200	35.300	35.400	35.500	35.600	35.1000	APP
8.39	Patient or Human Research Subject Release	P	P	P	N/A	P	P	U
8.40	Safety Procedures for Therapy Treatments where Patients are Hospitalized	N/A	N	N	N/A	N*	N	
8.41	Safety Checks, Device Calibration, Operation, and Inspection Procedures	N/A	N/A	N/A	P	Y	Y	
8.42	Mobile Medical Service	Y	Y	Y	Y	Y	Y	V
8.43	Transportation	N	N	N	N	N	N	W
8.44	Waste Management	P	P	P	P	P	P	X

* N/A for teletherapy and gamma stereotactic radiosurgery

Tables C.2 and C.3 are provided to assist in responding to items 5 through 11 on NRC Form 313.

Table C.2 Items 5 and 6 on NRC Form 313: Radioactive Material And Use.

Yes	Radioisotope	Form or Manufacturer/ Model No.	Maximum Quantity	Purpose of Use
	Any byproduct material identified in 10 CFR 35.100	Any	As needed	Any uptake, dilution, and excretion study approved in 10 CFR 35.100.
	Any byproduct material identified in 10 CFR 35.200	Check all that apply: ❒ Unit dosages only; ❒ Any except generators; ❒ Any	As needed	Any imaging and localization study approved in 10 CFR 35.200.
	Any byproduct material identified in 10 CFR 35.300	Check all that apply: ❒ Unit dosages only; ❒ Any	___ millicuries	Any radiopharmaceutical therapy procedure approved in 10 CFR 35.300. Check Box ❒ if patients will be hospitalized *until* they can be released pursuant to 10 CFR 35.75.

Yes	Radioisotope	Form or Manufacturer/ Model No.	Maximum Quantity	Purpose of Use
	Iodine-131	Any	___ millicuries	Check all that apply: ❒ Diagnosis and treatment of hyperthyroidism; ❒Treatment of cardiac dysfunction; ❒Thyroid carcinoma. Check Box ❒ if use will include activities greater than 33 millicuries per administration.
	Byproduct material identified in 10 CFR 35.400 Check all that apply: ❒ Ir-192; ❒ Cs-137; ❒ I-125; ❒ Other, describe	Sealed sources (Manufacturer _____, Model No._____)	___ millicuries	Any brachytherapy procedure approved in 10 CFR 35.400. Check Box ❒ if patients will be hospitalized *until* they can be released pursuant to 10 CFR 35.75.
	Strontium-90	Sealed sources (Manufacturer _____, Model No._____)	___ millicuries	Treatment of superficial eye conditions using an applicator distributed pursuant to 10 CFR 32.74 and approved in 10 CFR 35.400.
	Byproduct material identified in 10 CFR 35.500 Check all that apply: ❒ Gd-153; ❒ I-125; ❒ Other, describe	Sealed sources (Manufacturer _____, Model No._____)	___ curies per source and ___ curies total	Diagnostic medical use of sealed sources as approved in 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).

Yes	Radioisotope	Form or Manufacturer/ Model No.	Maximum Quantity	Purpose of Use
	Iridium-192	Sealed sources (Manufacturer _____, Model No._____)	___ curies per source and ___ curies total	One source for medical use described in 10 CFR 35.600, in a **Manufacturer** _____ **Model No.** _____ remote afterloading brachytherapy device. One source in its shipping container as necessary for replacement of the source in the remote afterloader device.
	Cobalt-60	Sealed sources (Manufacturer _____, Model No._____)	___ curies per source and ___ curies total	One source for medical use described in 10 CFR 35.600, in a **Manufacturer** _____ **Model No.** _____ teletherapy unit. One source in its shipping container as necessary for replacement of the source in the teletherapy unit.
	Cobalt-60	Sealed sources (Manufacturer _____, Model No._____)	___ curies per source and ___ curies total	For medical use described in 10 CFR 35.600, in a **Manufacturer** _____ **Model No.** _____ stereotactic radiosurgery device. Sources in the shipping container as necessary for replacement of the sources in the stereotactic radiosurgery device.
	Any byproduct material identified in 10 CFR 31.11	Prepackaged kits	___ millicuries	*In vitro* studies.
	Depleted uranium	Metal	___ kilograms	Shielding in a teletherapy unit.
	Depleted uranium	Metal	___ kilograms	Shielding in a linear accelerator.
	Cesium-137	Sealed sources (Manufacturer _____, Model No._____)	___ millicuries	Non-human use. For use in a **Manufacturer** _____ **Model No.** _____ for calibration and checking of licensee's survey instruments.
	Americium-241	Sealed sources (Manufacturer _____, Model No._____)	___ millicuries per source and ___ millicuries total	Use as an anatomical marker.

Yes	Radioisotope	Form or Manufacturer/ Model No.	Maximum Quantity	Purpose of Use
	Plutonium (principal radionuclide Pu-238)	Sealed sources	___ millicuries per source and ___ grams total	As a component of **Manufacturer** _____ **Model No.** _____, nuclear-powered cardiac pacemakers for clinical evaluation in accordance with manufacturer's protocol dated _____. This authorization includes: follow-up, explantation, recovery, disposal, and implantation.
	Other	Form or Manufacturer/ Model No. _____	___ millicuries	Purpose of use _____.

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal.

Item Number and Title	Suggested Response	Yes
Item 7: Radiation Safety Officer Name: _____	Attached Delegation of Authority and RSO agreement to be responsible for implementing the radiation protection program (see Appendix F).	❒
	Attached written certification, signed by a preceptor RSO, that the training and experience have been satisfactorily completed and that a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use licensee has been achieved.	❒
	Attached previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) that authorized the uses requested and on which the individual was specifically named as the RSO.	❒
	Attached copy of the certification(s) for the board(s) recognized by NRC as applicable to the types of use for which he or she has RSO responsibilities.	❒
	Attached description of the training and experience demonstrating that the proposed RSO is qualified by training and experience as applicable to the types of use for which he or she has RSO responsibilities. NRC Forms 313A and 313B may be used for this purpose (see Appendix G).	❒

Item Number and Title	Suggested Response	Yes
Item 7: Authorized Users Names and Requested Uses for Each Individual _____ _____	Attached written certification, signed by a preceptor AU physician, that the training and experience have been satisfactorily completed and that a level of competency sufficient to function independently as an AU for the medical uses authorized has been achieved.	❒
	AND	
	Attached previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) on which the physician was specifically named as an AU for the uses requested.	❒
	OR	
	Attached copy of the certification(s) for the board(s) recognized by NRC as applicable to the use requested.	❒
	OR	
	Attached description of the training and experience demonstrating that the proposed AU is qualified by training and experience for the use requested. NRC Forms 313A and 313B may be used for this purpose (see Appendix G).	❒

Item Number and Title	Suggested Response	Yes
Item 7: Authorized Nuclear Pharmacists Names: _____	Attached written certification, signed by a preceptor ANP, that the training and experience have been satisfactorily completed and that the individual has achieved a level of competency sufficient to function independently as an ANP.	❒
	AND	
	Attached previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) on which the individual was specifically named as an ANP.	❒
	OR	
	Attached copy of the certification(s) for the radiopharmacy board(s) recognized by NRC.	❒
	OR	
	Attached description of the training and experience demonstrating that the proposed ANP is qualified by training and experience. NRC Forms 313A and 313B may be used for this purpose (see Appendix G).	❒
Item 7: Authorized Medical Physicists Names: _____	Attached written certification, signed by a preceptor AMP, that the training and experience have been satisfactorily completed and that a level of competency sufficient to function independently as an AMP for the uses requested has been achieved.	❒
	AND	
	Attached previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) on which the individual was specifically named as an AMP for the uses requested.	❒
	OR	
	Attached copy of the certification(s) for the board(s) recognized by NRC.	❒
	OR	
	Attached description of the training and experience demonstrating that the proposed AMP is qualified by training and experience. NRC Forms 313A and 313B may be used for this purpose (see Appendix G).	❒

Item Number and Title	Suggested Response	Yes
Item 8: Safety Instruction for Individuals Working in or Frequenting Restricted Areas	The licensee must provide safety instruction as required by 10 CFR 19.12. Also, 10 CFR 35.310, 10 CFR 35.410 and 10 CFR 35.610 describe additional safety instruction requirements for individuals involved with therapeutic treatment of patients. 10 CFR 35.27 requires the licensee's AUs and ANPs to provide safety instruction to all personnel using byproduct material under their supervision. This training will be examined during inspections and should not be submitted in the license application.	N/A
Item 9: Facility Diagram	A diagram is enclosed that describes the facilities and identifies activities conducted in all contiguous areas surrounding the area(s) of use. Diagrams are drawn to a specified scale, or dimensions are indicated.	❒
	The following information is included:	
	• Descriptions of the area(s) assigned for receipt, storage, preparation, and administration of radioactive materials and the location for radioactive waste storage.	❒
	• Sufficient detail in the diagram to indicate locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety.	❒
	• Verification, if necessary, that ventilation systems ensure that effluents are within 10 CFR 20.1301 limits and the ALARA constraints for air emissions established under 10 CFR 20.1101(d) are met.	❒
	• Calculations of the maximum radiation levels expected in each area adjacent to teletherapy, gamma stereotactic, or remote afterloader units.	❒

Item Number and Title	Suggested Response	Yes
Item 9: Radiation Monitoring Instruments	The instrument types possessed, including the sensitivity and range for each type of radiation detected, are _____.	❒
	AND	
	If we possess only one survey instrument, we will obtain a backup survey instrument of comparable sensitivity and range when our survey instrument is being calibrated or repaired.	❒
	AND	
	Radiation monitoring instruments will be calibrated by a person authorized by NRC or an Agreement State to perform survey meter calibrations.	❒
	AND/OR	
	We have developed and will implement and maintain written survey meter calibration procedures in accordance with the requirements in 10 CFR 20.1101, that also meet the requirements of 10 CFR 35.61.	❒
Item 9: Dose Calibrator and Other Dosage Measuring Equipment	The instrument type possessed is _____.	❒
	AND	
	If we possess only one dose calibrator, we will obtain a backup dose calibrator when our dose calibrator is being calibrated or repaired and patient dosages are required to be measured.	❒
	AND	
	Dosage measuring equipment will be calibrated by a person authorized by NRC or an Agreement State to perform dosage measuring equipment calibrations.	❒
	AND/OR	
	We have developed and will implement and maintain written dosage measuring equipment calibration procedures in accordance with 10 CFR 35.41, that also meet the requirements in 10 CFR 35.60 and 10 CFR 35.63, as applicable.	❒

Item Number and Title	Suggested Response	Yes
Item 9: Dosimetry Equipment – Calibration and Use	The instrument type, manufacturer, and model number is _____	❒
	AND	
	We will calibrate dosimetry equipment in accordance with the requirements in 10 CFR 35.630.	❒
	AND	
	We have developed and will implement and maintain written therapy sealed source calibration and spot check procedures in accordance with 10 CFR 35.41, that also meet the requirements in 10 CFR 35.432, 10 CFR 35.632, 10 CFR 35.633, 10 CFR 35.635, 10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645 (as applicable to the type of medical use requested).	❒
Item 9: Other Equipment and Facilities	Attached is a description of additional facilities and equipment. These include:	
	• Fume hoods;	❒
	• Xenon traps;	❒
	• Emergency response equipment;	❒
	• Area radiation monitor;	❒
	• Remote handling tools;	❒
	• Source transport container;	❒
	• Patient viewing and intercom systems;	❒
	• Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room;	❒
	• Private rooms used for unsealed source therapy treatments;	❒
	• Methods for controlling occupancy for each restricted area;	❒
	• Mechanisms for ensuring that no two therapy units can be operated simultaneously if other radiation-producing equipment (e.g., linear accelerator, x-ray machine) is located in the treatment room;	❒
	• Mechanisms for ensuring that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons.	❒

Item Number and Title	Suggested Response	Yes
Item 10: Audit Program	The applicant's program for reviewing the content and implementation of its radiation protection program will be examined during inspections and should not be submitted in the license application.	N/A
Item 10: Occupational Dose	The facilities, if applicable, and equipment used for monitoring occupational exposure are _____ _____ **AND**	❒
	We have developed and will implement and maintain written procedures for monitoring occupational dose in accordance with 10 CFR 20.1101, that also meet the requirements in Subparts C and F of 10 CFR Part 20.	❒
Item 10: Public Dose	The applicant's program for controlling doses to individual members of the public will be examined during inspection and should not be submitted in the license application except as provided in response to Item 9.	N/A
Item 10: Minimization of Contamination	Attached is a description of how the facility design and the procedures for operation will minimize contamination of the facility and the environment, facilitate eventual decommissioning, and minimize the generation of radioactive waste.	❒
Item 10: Ordering and Receiving	The applicant's program for ordering and receiving licensed material will be examined during inspection and should not be submitted in the license application.	N/A
Item 10: Opening Packages	We have developed and will implement and maintain written package-opening procedures that meet the requirements of 10 CFR 20.1906.	❒
Item 10: Sealed Source Inventory	The applicant's program for inventorying sealed sources will be examined during inspection and should not be submitted in the license application.	N/A
Item 10: Use Records	The applicant's program for recording the use of licensed material will be examined during inspection and should not be submitted in the license application.	N/A
Item 10: Leak Tests	The applicant's program for leak testing sealed sources will be examined during inspection and should not be submitted in the license application.	N/A

Item Number and Title	Suggested Response	Yes
Item 10: Area Surveys	We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101, that also meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70.	❒
Item 10: Procedures for Administrations Requiring a Written Directive	We have developed and will implement and maintain written procedures for administrations requiring a written directive in accordance with 10 CFR 35.41.	❒
Item 10: Safe Use of Unsealed Licensed Material	We have developed and will implement and maintain procedures for safe use of unsealed licensed material that meet the requirements of 10 CFR 20.1101, 10 CFR 20.1301 and 10 CFR 35.69.	❒
Item 10: Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources	We will contract with personnel who are licensed by NRC or an Agreement State to install, maintain, adjust, repair, and inspect all therapy devices. **OR** Name of the proposed employee and types of activities requested: _____. **AND** Attached description of the training and experience demonstrating that the proposed employee is qualified by training and experience for the types of activities requested. **AND** Attached copy of the manufacturer's training certification and an outline of the training.	❒ ❒ ❒ ❒
Item 10: Spill Procedures	We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10CFR 20.1101.	❒
Item 10: Emergency Response for Sealed Sources or Devices Containing Sealed Sources	We have developed and will implement and maintain written procedures for safe response to emergencies involving sealed sources in accordance with 10 CFR 20.1101 and 10 CFR 35.12, that also meet the requirements of 10 CFR 35.410 and 10 CFR 35.610 (as applicable). **AND** Attached procedures developed in accordance with 10 CFR 35.610(a)(4)	❒ ❒

Item Number and Title	Suggested Response	Yes
Item 10: Patient or Human Research Subject Release	We have developed and will provide written instructions to patients or human research subjects (or their parent or guardian), released pursuant to 10 CFR 35.75, that also meet the requirements in 10 CFR 35.75.	❒
Item 10: Safety Procedures for Treatments Where Patients are Hospitalized	The applicant's responses to "Other Equipment and Facilities" and "Occupational Dose" will be considered in response to this item.	❒
Item 10: Procedures for Device Calibration, Safety Checks, Operation, and Inspection	We have developed and will implement and maintain written procedures for safe medical use of sealed sources and devices and calibration of sources in accordance with 10 CFR 20.1101 and 10 CFR 35.12, that also meet the requirements of the applicable section(s) of 10 CFR Part 35, Subparts G and H. **AND** Attached procedures developed in accordance with 10 CFR 35.610, 10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645, as applicable.	❒ ❒
Item 10: Mobile Medical Service	Attached is the information requested in Appendix V to NUREG-1556, Volume 9.	❒
Item 10: Transportation	The applicant's program for transportation will be examined during inspection and should not be submitted in the license application.	N/A
Item 10: Waste Management	We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of Subpart K to 10 CFR Part 20 and 10 CFR 35.92.	❒

Following are several examples of medical licenses. The license conditions are not necessarily the most current conditions placed on NRC licenses and may change over time based on the most recent version of NUREG-1556, Vol. 20, "Guidance About Administrative Licensing Procedures."

NRC FORM 374 U.S. NUCLEAR REGULATORY COMMISSION PAGE 1 OF 2 PAGES

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Sample Gamma Knife	3. License Number 99-12345-01
2. 100 Main Street King of Prussia, Pennsylvania	4. Expiration Date May 31, 2002
	5. Docket No. 030-54321 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Cobalt 60	A. Sealed Sources (Manufacturer _____ Model No. _____)	A. _____ curies per source and _____ curies total

9. Authorized Use

A. For medical use described in 10 CFR 35.600, in a _____ Stereotactic Radiosurgery device. Sources in the shipping container as necessary for replacement of the sources in the stereotactic radiosurgery device.

CONDITIONS

10. Licensed material may be used only at the licensees facilities located at 100 Main Street, King of Prussia, Pennsylvania.

11. A. License material listed in item 6 above is only authorized for use by, or under the supervision of, John Smith, M.D. and Jessica Water, M.D.

B. The Medical Physicists for this license are Kimberly Therapy, Ph.D. and Ronald Stereo, M.S.

12. The Radiation Safety Officer for this license is Kimberly Therapy, Ph.D.

13. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, “Packaging and Transportation of Radioactive Material.”

NRC FORM 374A U.S. NUCLEAR REGULATORY COMMISSION	PAGE 2 OF 2 PAGES
MATERIALS LICENSE **SUPPLEMENTARY SHEET**	License Number 99-12345-01 Docket or Reference Number 030-54321

14. Except as specifically provided otherwise, in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated December 15, 1996
B. Letter dated March 4, 1997
C. Letter dated May 8, 1997

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: _____ By: _____

Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

NRC FORM 374 U.S. NUCLEAR REGULATORY COMMISSION PAGE 1 OF 5 PAGES

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

APPENDIX C

Licensee	
1. Sample Medical Institution Limited	3. License Number 99-02120-01
2. 1234 Main Street Anytown, Pennsylvania 02120	4. Expiration Date March 31, 2009
	5. Docket No. 030-02120 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material identified in 10 CFR 35.100	A. Any	A. As needed
B. Any byproduct material identified in 10 CFR 35.200	B. Any, except generators	B. As needed
C. Any byproduct material identified in 10 CFR 35.300	C. Any	C. 300 millicuries
D. Cesium 137	D. Sealed sources (Manufacturer xxx, Model No. yyy)	D. 500 millicuries
E. Gadolinium 153	E. Sealed sources (Manufacturer xxx, Model No. yyy)	E. 0.5 curies per source and 1 curie total
F. Any byproduct material identified in 10 CFR 31.11	F. Prepackaged Kits	F. 50 millicuries
G. Cesium-137	G. Sealed source (Manufacturer aaa, Model No. bbb)	G. 200 millicuries
H. Americium-241	H. Sealed sources (Manufacturer zzz, Model No. ccc)	H. _____ millicuries per source and _____ millicuries total
I. Depleted Uranium	I. Metal	I. 99 kilograms

NRC FORM 374A U.S. NUCLEAR REGULATORY COMMISSION PAGE 2 OF 5 PAGES

MATERIALS LICENSE SUPPLEMENTARY SHEET	License Number 99-02120-01
	Docket or Reference Number 030-02120

J. Iridium-192	J. Sealed Sources (Manufacturer xxx, Model No. xxx)	J. 10 curies per source and 20 curies total

Note: **Insert total possession limit in items 8.C, D, F and G. Insert manufacturer and model number of sealed sources in parenthesis in items 7.D, E, G, H, and J. Insert activity per source and total activity for sealed sources in items 8.E, H, and J. Depleted uranium should not exceed 999 kilograms in item 8.I. At 1,000 kilograms, a licensee is required to file a statement annually regarding foreign origin source material; see 40.64(b).**

Note: **Insert manufacturer and model number of device in items 9.G and J. Americium-241 in item 6.H is not necessarily covered by 10 CFR 35.67 (Calibration and Reference Sources), therefore it needs to be listed.**

9. Authorized Use

   A. Any uptake, dilution and excretion study approved in 10 CFR 35.100.

   B. Any imaging and localization study approved in 10 CFR 35.200.

   C. Any radiopharmaceutical therapy procedure approved in 10 CFR 35.300.

Note: **Insert "for which the patient can be released under the provisions of 10 CFR 35.75" if the licensee is performing outpatient therapy procedures only.**

   D. Any brachytherapy procedure approved in 10 CFR 35.400.

Note: **Insert "for which the patient can be released under the provisions of 10 CFR 35.75" if the licensee is performing outpatient therapy procedures only.**

   E. Diagnostic medical use of sealed sources approved in 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).

   F. *In vitro* studies.

   G. Non-human use. For use in a_____Model_____for calibration and checking of licensee's survey instruments.

   H. Use as an anatomical marker.

   I. Shielding in a linear accelerator.

   J. One source for medical use described in 10 CFR 35.600, in a _____ High Dose Rate Remote Afterloading Brachytherapy Device. One source in its shipping container as necessary for replacement of the source in the remote afterloader device.

APPENDIX C

NRC FORM 374A	U.S. NUCLEAR REGULATORY COMMISSION	PAGE 3 OF 5 PAGES
MATERIALS LICENSE **SUPPLEMENTARY SHEET**		License Number 99-02120-01 Docket or Reference Number 030-02120

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 1234 Main Street, Anytown, Pennsylvania.

11. The Radiation Safety Officer for this license is Melba Physicist, M.S.

12 The Medical Physicist for this license is Cecil Source, Ph.D.

Note: **There must be at least one authorized user listed in Condition 13 who is authorized for each of the materials and uses listed in item 6. For example: If John Therapy, M.D. left the institution and no authorized user who qualified for his material and use authorizations was added to the license, 35.400 materials, the remote afterloader, and DU would need to be removed from the license. If Thomas Group, D.O. left, however, no changes to the licensees' materials use authorization would be needed.**

13. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized Users	Material and Use
Jane Diagnostic, M.D.	35.100; 35.200; 35.300; 35.500; *In vitro* studies; Cesium-137; Americium-241
Thomas Group, D.O.	35.100; 35.200; Strontium-89 for uses identified in 35.300
Gilbert Lawrence, M.D.	35.100; 35.200; 35.500; Iodine-131 for treatment of hyperthyroidism and cardiac dysfunction
John Therapy, M.D.	35.400; Iridium-192 for uses in a High Dose Rate Remote Afterloading Brachytherapy Device; Depleted Uranium
James Pathology, Ph.D.	*In vitro* studies

14. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d), 40.36(b), and 70.25(d) for establishing financial assurance for decommissioning.

Note: **The Cesium-137 sealed source, listed in Item 6.G and the Americium source in Item 6.H, are not covered by 10 CFR Part 35 (35.65, 35.400, 35.500 and 35.600) and require that license conditions 15-18 regarding uses of sealed sources be listed on the license. Sealed source conditions need not be listed on a medical license unless the license authorizes a sealed source not covered by Part 35.**

NRC FORM 374A	U.S. NUCLEAR REGULATORY COMMISSION	PAGE 4 OF 5 PAGES

MATERIALS LICENSE SUPPLEMENTARY SHEET	License Number 99-02120-01
	Docket or Reference Number 030-02120

15. A. Sealed sources and detector cells containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed 3 years.

B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed three months.

C. In the absence of a certificate from a transferor indicating that a leak test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.

E. Sealed sources and detector cells need not be leak tested if:

(i) they contain only hydrogen-3; or
(ii) they contain only a radioactive gas; or
(iii) the half-life of the isotope is 30 days or less; or
(iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or
(v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transfer to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

F. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source or detector cell shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the appropriate U. S. Nuclear Regulatory Commission, Regional Office referenced in Appendix D of 10 CFR Part 20. The report shall specify the source or detector cell involved, the test results, and corrective action taken.

G. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

NRC FORM 374A U.S. NUCLEAR REGULATORY COMMISSION	PAGE 5 OF 5 PAGES
MATERIALS LICENSE **SUPPLEMENTARY SHEET**	License Number 99-02120-01
	Docket or Reference Number 030-02120

16. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee.

17. The licensee shall not acquire licensed material in a sealed source or device unless the source or device has been registered with the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.

18. The licensee shall conduct a physical inventory every six months to account for all sealed sources and devices containing licensed material received and possessed.

19. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

20. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A Application dated June 10, 1998
B Letter dated November 18, 1998
C Letter dated March 16, 1999

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: March 20, 1999

By: Original signed by

Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

NRC FORM 374 U.S. NUCLEAR REGULATORY COMMISSION PAGE 1 OF 2 PAGES

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

APPENDIX C

Licensee	In accordance with the application dated September 30, 1994
1. Sample Pacemaker License	3. License Number SNM-22160 is amended in its entirety to read as follows:
2. 100 Medical Center Drive King of Prussia, Pennsylvania 19406	4. Expiration Date October 31, 1999
	5. Docket No. 070-22160 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Plutonium (principal radionuclide Pu-238)	A. Sealed source (Manufacturer xxx, Model No. yyy)	A. _____ milligrams per source and _____ grams total

9. Authorized Use

A. As a component of _____ nuclear-powered pacemakers for clinical evaluation in accordance with manufacturer's protocol dated _____. This authorization includes: follow-up, explanation, recovery, disposal and implantation.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 100 Medical Center Drive, King of Prussia, Pennsylvania.
11. The Radiation Safety Officer for this license is Chief Radiologist, M.D.
12. The physicians responsible for implantation, follow-up, explanation, and return of nuclear-powered pacemakers to the manufacturer for proper disposal are Chief Cardiosurgeon, M.D.
13. The specified possession limit for nuclear-powered pacemakers includes all licensed material possessed by the licensee under this license whether in storage, implanted in patients, or otherwise in use.
14. The licensee shall continue patient follow-up and replacement procedures for the nuclear-powered pacemaker during the life of the patient. Procedures for recovery and authorized disposal of the nuclear-powered pacemaker by return to the manufacturer shall be followed upon the death of the patient.
15. The licensee shall report to the U.S. Nuclear Regulatory Commission's Regional Office, referenced in Appendix D of 10 CFR Part 20, within 10 days after discovery of loss of contact with a nuclear-powered pacemaker patient.
16. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

NRC FORM 374A U.S. NUCLEAR REGULATORY COMMISSION PAGE 2 OF 2 PAGES

MATERIALS LICENSE SUPPLEMENTARY SHEET	License Number SNM-22160
	Docket or Reference Number 070-22160

17. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

18. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

    A Application dated September 30, 1994
    B Letter received October 15, 1994

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: _____ By: _____

Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

NRC FORM 374 U.S. NUCLEAR REGULATORY COMMISSION PAGE 1 OF 5
PAGES

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Sample Medical - Broad Scope	3. License Number 99-02110-01
2. 300 Main Street Anytown, Pennsylvania 02300	4. Expiration Date October 31, 2004
	5. Docket No. 030-02110 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material with atomic number 1 through 83	A. Any	A. 200 millicuries per radionuclide and 15 curies total
B. Any byproduct material with atomic number 3 through 83	B. Sealed Sources	B. 1.5 curies per radionuclide and 15 curies total
C. Hydrogen 3	C. Any	C. 2 curies
D. Carbon 14	D. Any	D. 1 curie
E. Phosphorus 32	E. Any	E. 2 curies
F. Sulfur 35	F. Any	F. 2 curies
G. Chromium 51	G. Any	G. 500 millicuries
H. Molybdenum 99	H. Any	H. 10 curies
I. Technetium 99m	I. Any	I. 10 curies
J. Iridium 192	J. Sealed Sources (Manufacturer xxx, Model No. yyy)	J. 12 curies per source and 24 curies total

9. Authorized Use

Note: **Insert the sealed source manufacturer and model number in 7.J parenthesis above. Insert HDR afterloading unit manufacturer and model number in blank in 9.J below.**

NRC FORM 374A U.S. NUCLEAR REGULATORY COMMISSION	PAGE 2 OF 5 PAGES
MATERIALS LICENSE **SUPPLEMENTARY SHEET**	License Number 99-02110-01 Docket or Reference Number 030-02110

A. through I. Medical diagnosis, therapy and research in humans. Research and development as defined in 10 CFR 30.4, including animal studies; instrument calibration; student instruction; and *in vitro* studies.

J. One source for medical use described in 10 CFR 35.600, in a remote afterloading brachytherapy device. One source in its shipping container as necessary for replacement of the source in the remote afterloader device.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities at 300 Main Street, Anytown, Pennsylvania.

11 A. Licensed material shall be used by, or under the supervision of, individuals designated in writing by the Radiation Safety Committee, Albert Einstein, M.D., Ph.D., Chairperson.

B. The use of licensed material in or on humans shall be by a physician, dentist, or podiatrist as defined in 10 CFR 35.2.

C. Individuals designated in writing to work as authorized users or authorized nuclear pharmacists, as defined in 10 CFR 35.2, shall meet the training and experience criteria established in 10 CFR Part 35, Subparts B, and D through H, and shall be designated by the licensee's Radiation Safety Committee.

D. The Radiation Safety Officer for this license is Patty Melt, Ph.D.

E. The Medical Physicist for this license is Melba Toast, M.S.

12. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

13. The licensee shall conduct a physical inventory every six months to account for all sealed sources and devices containing licensed material.

NRC FORM 374A U.S. NUCLEAR REGULATORY COMMISSION	PAGE 3 OF 5 PAGES
MATERIALS LICENSE **SUPPLEMENTARY SHEET**	License Number 99-02110-01 Docket or Reference Number 030-02110

14. A. Sealed sources and detector cells containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed 3 years.

B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed three months.

C. In the absence of a certificate from a transferor indicating that a leak test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.

E. Sealed sources and detector cells need not be leak tested if:

(i) they contain only hydrogen-3; or
(ii) they contain only a radioactive gas; or
(iii) the half-life of the isotope is 30 days or less; or
(iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or
(v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transfer to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

F. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source or detector cell shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the appropriate U. S. Nuclear Regulatory Commission, Regional Office referenced in Appendix D of 10 CFR Part 20. The report shall specify the source or detector cell involved, the test results, and corrective action taken.

G. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

NRC FORM 374A U.S. NUCLEAR REGULATORY COMMISSION	PAGE 4 OF 5 PAGES
MATERIALS LICENSE **SUPPLEMENTARY SHEET**	License Number 99-02110-01 Docket or Reference Number 030-02110

15. A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperatures from exceeding that specified in the certificate of registration referred to in 10 CFR 32.210

    B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.

16. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.

17. The licensee is authorized to hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal in ordinary trash, provided:

    A. Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.

    B. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

    C. A record of each such disposal permitted under this License Condition shall be retained for 3 years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

18. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific conditions of this license.

19. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, “Packaging and Transportation of Radioactive Material.”

NRC FORM 374A U.S. NUCLEAR REGULATORY COMMISSION	PAGE 5 OF 5 PAGES
MATERIALS LICENSE **SUPPLEMENTARY SHEET**	License Number 99-02110-01 Docket or Reference Number 030-02110

20. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

    A. Application dated April 23, 1994
    B. Letter dated June 8, 1994
    C. Letter dated July 26, 1994
    D. Letter dated August 8, 1994
    E. Letter dated October 4, 1994

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: _____ By: _____

Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

NRC FORM 374 U.S. NUCLEAR REGULATORY COMMISSION PAGE 1 OF 2 PAGES

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Sample Teletherapy	3. License Number 99-02300-01
2. 200 Cobalt Street	4. Expiration Date October 31, 2004
King of Prussia, Pennsylvania 02300	5. Docket No. 030-02300
	Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Cobalt-60	A. Sealed sources (Manufacturer yyy, Model No. xxx)	A. 5,500 curies per source and 11,000 curies total
B. Depleted Uranium	B. Metal	B. ____ kilograms

9. Authorized Use

Note: **Insert teletherapy sealed source manufacturer and model number in 7.A parenthesis above. Depleted uranium possession limit in 8.B above may not exceed 999 kilograms. Insert teletherapy unit/device manufacturer and model number in blank 9.A below.**

A. One source for medical use described in 10 CFR 35.600, in a _____ teletherapy unit. One source in its shipping container as necessary for replacement of the source in the teletherapy unit.

B Shielding in a teletherapy unit.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 200 Cobalt Street, King of Prussia, Pennsylvania.

11. The Radiation Safety Officer for this license is Sarah Smith, M.S.

12. The Medical Physicist for this license is Sarah Smith, M.S.

13. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized Users	Material and Use
David Jones, M.D.	Cobalt-60 for uses in a Teletherapy Unit; Depleted uranium

NRC FORM 374A U.S. NUCLEAR REGULATORY COMMISSION	PAGE 2 OF 2 PAGES
MATERIALS LICENSE **SUPPLEMENTARY SHEET**	License Number 99-02300-01 Docket or Reference Number 030-02300

14. The licensee is exempted from decommissioning financial assurance requirements for possession of licensed material in sealed sources in quantities greater than the limits in 10 CFR 30.35(d) for the purpose of source changes only. This exemption is granted for no more than 30 days for any one source change.

15. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

16. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licencee's application and correspondence are more restrictive than the regulations.

A. Application dated March 4, 1994
B. Letter dated May 12, 1994
C. Letter dated October 7, 1994

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: _____ By: Original Signed by

Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

NRC FORM 374 U.S. NUCLEAR REGULATORY COMMISSION PAGE 1 OF 2 PAGES

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	In accordance with the application dated July 17, 1994
1. Sample *In Vitro* Testing Laboratory	3. License Number 99-02410-01 is amended in its entirety to read as follows:
2. 1234 Clinical Way Petri, Delaware 02410	4. Expiration Date September 30, 2004
	5. Docket No. 030-02410 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Hydrogen-3	A. Any	A. 5 millicuries
B. Carbon-14	B. Any	B. 5 millicuries
C. Phosphorus-32	C. Any	C. 5 millicuries
D. Iron-59	D. Any	D. 2 millicuries
E. Iodine-125	E. Labeled compounds	E. 10 millicuries

9. Authorized Use

A. through E. *In vitro* laboratory studies.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 1234 Clinical Way, Petri, Delaware.

11. A. Licensed material shall be used by, or under the supervision of, Maria Kitt, Ray D. O'Tracer or Otto Radiograph.

    B. The Radiation Safety Officer for this license is Maria Kitt.

12. Licensed material shall not be used in or on human beings.

13. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash, provided:

    A. Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.

    B. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

NRC FORM 374A U.S. NUCLEAR REGULATORY COMMISSION	PAGE 2 OF 2 PAGES
MATERIALS LICENSE **SUPPLEMENTARY SHEET**	License Number 99-02410-01
	Docket or Reference Number 030-02410
	Amendment No. 01

C. A record of each such disposal permitted under this License Condition shall be retained for 3 years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

    A. Application dated July 17, 1994
    B. Letter dated September 8, 1994

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: _____ By: _____

Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

Appendix D

Information Needed for Transfer of Control

Information Needed for Transfer of Control

Definitions:

Control: Control of a license is in the hands of the person or persons who are empowered to decide when and how that license will be used. That control is to be found in the person or persons who, because of ownership or authority explicitly delegated by the owners, possess the power to determine corporate policy and thus the direction of the activities under the license.

Transferee: A transferee is an entity that proposes to purchase or otherwise gain control of an NRC-licensed operation.

Transferor: A transferor is an NRC licensee selling or otherwise giving up control of a licensed operation.

Licensees must provide full information and obtain NRC's ***prior written consent*** before transferring control of the license. Provide the following information concerning changes of control by the applicant (transferor and/or transferee, as appropriate). If any items are not applicable, so state.

1. Provide a complete description of the transaction (transfer of stocks or assets, or merger). Indicate whether the name has changed and include the new name. Include the name and telephone number of a licensee contact who NRC may contact if more information is needed.
2. Describe any changes in personnel or duties that relate to the licensed program. Include training and experience for new personnel.
3. Describe any changes in the organization, location, facilities, equipment or procedures that relate to the licensed program.
4. Describe the status of the surveillance program (surveys, wipe tests, quality control) at the present time and the expected status at the time that control is to be transferred.
5. Confirm that all records concerning the safe and effective decommissioning of the facility will be transferred to the transferee or to NRC, as appropriate. These records include documentation of surveys of ambient radiation levels and fixed and/or removable contamination, including methods and sensitivity.
6. Confirm that the transferee will abide by all constraints, conditions, requirements and commitments of the transferor or that the transferee will submit a complete description of the proposed licensed program.

Appendix E

Guidance on Financial Assurance Determination

Guidance on Financial Assurance Determination

Determining Need for Financial Assurance for Decommissioning

The half-lives of unsealed byproduct material used by medical licensees have traditionally been less than 120 days. Therefore, most medical use applicants need only consider licensed material in sealed sources to evaluate the need for financial assurance. Use Table E.1 to determine if financial assurance is required for the sealed sources listed. If requesting sealed sources other than those listed or any other unsealed byproduct material with a half-life greater than 120 days, refer to 10 CFR 30.35 and Appendix B to Part 30 for possession limits requiring financial assurance. The sum of the fractions procedure is also depicted in Table E.1 and must be used to determine the need for financial assurance for both sealed and unsealed byproduct material.

Table E.1 Worksheet for Determining Need for Financial Assurance for Sealed Sources.

Step Number	Description	Cobalt-60	Cesium-137	Strontium-90
1	Activity possessed, in Curies*			
2	Activity requiring financial assurance, in Curies	10,000	100,000	1,000
3	Divide data in Step 1 by data in Step 2 = FRACTION			
4	Add the fractions determined in Step 3			

* This table uses only conventional units. The conversion to the International System of units (SI) is: 1 Curie = 37 gigabecquerels.

As 10 CFR 30.35 describes, if the sum of the fractions is greater than or equal to 1, the applicant will need to submit financial assurance. RG 3.66[1], "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72," dated June 1990, provides sample documents for financial mechanisms. Because a Statement of Intent for government licensees is not described in RG 3.66, the recommended wording for this statement is shown below.

[1] See the Notice of Availability (inside front cover of this report) to obtain copies of RG 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72," dated June 1990.

Suggested Wording for a Statement of Intent for a Government Licensee

[DATE]
TO: U. S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555 [or appropriate regional address]

STATEMENT OF INTENT

As [TITLE] of [LICENSEE NAME], I exercise express authority and responsibility to approve funding for decommissioning activities associated with operations authorized by U. S. Nuclear Regulatory Commission Material License No._____. This authority is established by [NAME OF DOCUMENT(S) GOVERNING CONTROL OF FUNDS]. Within this authority, I intend to have funds made available when necessary, in an amount up to [DOLLAR AMOUNT] to decommission [DESCRIPTION OF FACILITIES]. I intend to request and obtain these funds sufficiently in advance of decommissioning to prevent delay of required activities.

A copy of [NAME OF DOCUMENTS] is attached as evidence that I am authorized to represent [LICENSEE NAME] in this transaction.

[SIGNATURE]
[NAME]
[TITLE]

Attachment: As stated

Appendix F

Typical Duties and Responsibilities of the Radiation Safety Officer and Sample Delegation of Authority

Typical Duties and Responsibilities of the Radiation Safety Officer and Sample Delegation of Authority

Model RSO Duties and Responsibilities

The RSO's duties and responsibilities include ensuring radiological safety and compliance with NRC and DOT regulations and the conditions of the license (see Figure 8.7). This model provides acceptable procedures for the RSO's duties and responsibilities. You may either adopt these model procedures or develop your own procedure to meet the requirements of 10 CFR 35.24. Typically, these duties and responsibilities include ensuring the following:

- Activities involving licensed material that the RSO considers unsafe are stopped;
- Radiation exposures are ALARA;
- Up-to-date radiation protection procedures in the daily operation of the licensee's byproduct material program are developed, distributed, and implemented;
- Possession, use, and storage of licensed material is consistent with the limitations in the license, the regulations, the SSDR Certificate(s), and the manufacturer's recommendations and instructions;
- Individuals installing, relocating, maintaining, adjusting, or repairing devices containing sealed sources are trained and authorized by an NRC or Agreement State license;
- Personnel training is conducted and is commensurate with the individual's duties regarding licensed material;
- Documentation is maintained to demonstrate that individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits or that personnel monitoring devices are provided;
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained;
- Licensed material is properly secured;
- Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public;
- Proper authorities are notified of incidents such as loss or theft of licensed material, damage to or malfunction of sealed sources, and fire;
- Medical events and precursor events are investigated and reported to NRC. Cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken;

- Audits of the radiation protection program are performed at least annually and documented;
- If violations of regulations, license conditions, or program weaknesses are identified, effective corrective actions are developed, implemented, and documented;
- Licensed material is transported, or offered for transport, in accordance with all applicable DOT requirements;
- Licensed material is disposed of properly;
- Appropriate records are maintained;
- An up-to-date license is maintained and amendment and renewal requests are submitted in a timely manner.

Model Delegation of Authority

Memo To: Radiation Safety Officer
From: Chief Executive Officer
Subject: Delegation of Authority

You, _____, have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the radiation protection program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations where justified by radiation safety. You are required to notify management if staff do not cooperate and do not address radiation safety issues. In addition, you are free to raise issues with the Nuclear Regulatory Commission at anytime. It is estimated that you will spend _____ hours per week conducting radiation protection activities.

_____
Signature of Management Representative

I accept the above responsibilities,
_____
Signature of Radiation Safety Officer

cc: Affected department heads

Appendix G

Documentation of Training and Experience

Documentation of Training and Experience

General Guidance

The required training and experience described in 10 CFR Part 35 must be obtained within the 7 years preceding the date of the application, or the individual must document having had related continuing education, retraining, and experience since obtaining the required training and experience. Complete retraining is neither practical nor necessary in most cases. Examples of acceptable continuing education and experience include the following:

- Successful completion of classroom and laboratory review courses that include radiation safety practices relative to the proposed type of authorized medical use;
- Practical and laboratory experience with patient procedures using radioactive material for the same use(s) for which the applicant is requesting authorization;
- Practical and laboratory experience under the supervision of an AU at the same or another licensed facility that is authorized for the same use(s) for which the applicant is requesting authorization;
- For therapy devices, experience with the therapy unit and/or comparable linear accelerator experience and completion of an in-service review of emergency procedures relative to the therapy unit to be used by the applicant.

The simplest and most straightforward method of demonstrating acceptable training and experience is through certification by a professional board recognized by NRC. Equally straightforward evidence is that the applicant is listed as a user on an NRC or Agreement State license or permit issued by a medical broad scope or master materials licensee, provided that the applicant is authorized for the same types of use(s) requested in the application under review, and that the applicant meets the recentness of training criteria described in 10 CFR 35.59. For users who have been previously authorized under a medical broad scope or master materials license, the applicant should submit either verification of previous authorization(s) granted by the broad scope or master materials licensee or evidence of acceptable training and experience.

NRC recognizes supervised work experience, such as that described in 10 CFR 35.290(c), conducted under a preceptor in a licensed material use program. A preceptor is an AU who provides frequent direction, instruction, and direct oversight of the student as the student completes the required work experience in the use of byproduct material. Preceptorships may occur at various licensed facilities, from a large teaching university hospital to a small private practice. However, work experience for sealed source therapy, as described in 10 CFR 35.490(b)(1) and 10 CFR 35.690(b)(1) must have been gained at a medical institution. When the supervised work experience is complete, the applicant should submit either the

preceptor forms, NRC Forms 313A and 313B as attachments to NRC Form 313, "Application for Material License," or a letter from the preceptor that indicates that the applicant has obtained all required experience elements.

There is no NRC *requirement* that an AU must render an interpretation of a diagnostic image or results of a therapeutic procedure. NRC recognizes that the AU may or may not be the physician who interprets such studies. Additionally, NRC regulations do not restrict who can read and interpret diagnostic scans or the results of therapeutic procedures involving the administration of byproduct material to individuals. The Technical Assistance Request response dated June 15, 1995, "Interpretation of the Requirements for Physicians who Interpret Diagnostic Imaging Scans," provides additional guidance on this issue.

NRC Form 313A **U.S. Nuclear Regulatory Commission**

TRAINING AND EXPERIENCE

Note: Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulations.

1. Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., 10 CFR 35.50) _____

2. For Physicians, State or Territory Where Licensed _____

3. Certification

Specialty Board	Category	Month and Year Certified

4. Classroom and Laboratory Training

Description of Training	Location	Clock Hours	Dates of Training
Radiation Physics and Instrumentation			
Radiation Protection			
Mathematics Pertaining to the Use and Measurement of Radioactivity			
Radiation Biology			
Chemistry of Byproduct Material for Medical Use			
Other			

5. Work Experience with Radiation. (Actual use of radionuclides or equivalent experience)

Description of Experience	Name of Supervising Individual(s)	Location and Corresponding Materials License Number	Clock Hours and Dates

6. Formal Training (*Note:* To be completed by applicants requesting 10 CFR 35.400 and/or 10 CFR 35.600 medical uses.)			
Degree, Area of Study	**Name of Program and Location with Corresponding Materials License Number**	**Dates**	**Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education) and the Applicable Regulation (e.g., 10 CFR 35.490).**

7. __(Yes/No)__The individual named in item 1 of this form is competent to function independently as an authorized _____.

Note: **Response to Item 7 is applicable to proposed authorized users, medical physicists, or radiation safety officer for the type of medical use requested.**

8. The training and experience indicated above was obtained under the supervision of:	**10. Preceptor's Signature**
_____ a. Name of Supervisor	
_____ b. Mailing Address	**11. Preceptor's Name (Printed Clearly)**
_____ c. City	
9. Materials License Number	**12. Date**

NRC Form 313B **U.S. Nuclear Regulatory Commission**

PRECEPTOR STATEMENT

Note: Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulations.

Supplement B must be completed by the individual's preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

1. Name of Individual, Proposed Authorization (e.g., Authorized User), and Applicable Training Requirements (e.g., 10 CFR 35.490):

_____
Name, Proposed Authorization, and Applicable Training Requirements

_____
Street Address

_____ _____ _____
City State Zip Code

2. Supervised Experience of Above Named Individual

Radionuclide	Type of Use	Number of Cases Involving Personal Participation	Location and Corresponding Materials License Number, Dates, and Clock Hours of Experience

3. _____ (Yes/No) **The individual named in item 1. of this form is competent to operate independently a nuclear pharmacy.**
Note: **Response to Item 3. is only applicable to proposed authorized nuclear pharmacists.**

4. The training and experience indicated above was obtained under the supervision of:

_____
a. Name of Supervisor

_____
b. Mailing Address

_____
c. City

6. Preceptor's Signature

7. Preceptor's Name (Printed Clearly)

5. Materials License Number

8. Date

Appendix H

Model Training Program

Model Training Program

This model provides acceptable procedures for training.

Model Training Program for Medical Uses of Radionuclides, Sealed Sources, and Medical Devices Containing Sealed Sources

Personnel will receive instruction before assuming duties with, or in the vicinity of, radioactive materials during annual refresher training and whenever there is a significant change in duties, regulations, terms of the license, or type of radioactive material or therapy device used. Records of worker training will be maintained for at least 3 years. The training records will include the date of the instruction or training and the name(s) of the attendee(s) and instructor(s).

Training for Individuals Involved in the Usage of Byproduct Material

We will instruct the professional staff (e.g., AU, AMP, ANP, RSO, nurse, dosimetrist, technologist, therapist) who provide or are involved in the care of patients during diagnostic or therapeutic procedures in the following topics, *commensurate with his/her duties*:

- Basic radiation biology, e.g., interaction of ionizing radiation with cells and tissues (10 CFR 19.12);
- Basic radiation protection to include concepts of time, distance, and shielding (10 CFR 19.12);
- Concept of maintaining exposure ALARA (10 CFR 19.12, 10 CFR 20.1101);
- Risk estimates, including comparison with other health risks (10 CFR 19.12);
- Posting requirements (10 CFR 20.1902);
- Proper use of personnel dosimetry (when applicable) (10 CFR 20.1201);
- Access control procedures (10 CFR 20.1601, 10 CFR 20.1802);
- Proper use of radiation shielding, if used (10 CFR 19.12);
- Patient release procedures (10 CFR 35.75);
- Instruction in procedures for notification of the RSO and AU, when responding to patient emergencies or death, to ensure that radiation protection issues are identified and addressed in a timely manner. The intent of these procedures should in no way interfere with or be in lieu of appropriate patient care (10 CFR 19.12, 10 CFR 35.310, 10 CFR 35.410, 10 CFR 35.610);
- Occupational dose limits and their significance (10 CFR 20.1201);
- Dose limits to the embryo/fetus, including instruction on declaration of pregnancy (10 CFR 20.1208);

- Worker's right to be informed of occupational radiation exposure (10 CFR 19.13);
- Each individual's obligation to report unsafe conditions to the RSO (10 CFR 19.12);
- Applicable regulations, license conditions, information notices, bulletins, etc. (10 CFR 19.12);
- Where copies of the applicable regulations, the NRC license, and its application are posted or made available for examination (10 CFR 19.11);
- Proper recordkeeping required by NRC regulations (10 CFR 19.12, 10 CFR 35.27);
- Appropriate surveys to be conducted, including surveys of all material leaving radioactive material areas (10 CFR 20.1501);
- Proper use of required survey instruments (10 CFR 20.1501);
- Emergency procedures (10 CFR 19.12);
- Decontamination and release of facilities and equipment (10 CFR 20.1406, 10 CFR 30.36);
- Dose to individual members of the public (10 CFR 20.1301);
- Licensee's operating procedures (e.g., survey requirements, instrument calibration, waste management, sealed source leak testing) (10 CFR 35.27).

Training for the Staff Directly Involved in Administration to or Care of Patients Administered Therapeutic Quantities of Byproduct Material (Including Greater than 30 microcuries of I-131), or Therapeutic Treatment Planning

In addition to the topics identified above, we will instruct staff involved in the therapy treatment of patients (e.g., nursing, RSO, AMP, AU, and dosimetrist) in the following topics, *commensurate with his/her duties*:

- Leak testing of sealed sources (10 CFR 35.67);
- Emergency procedures (including emergency response drills) (10 CFR 35.310, 10 CFR 35.410, 10 CFR 35.610);
- Operating instructions (10 CFR 35.27, 10 CFR 35.610);
- Computerized treatment planning system (10 CFR 35.657);
- Dosimetry protocol (10 CFR 35.610);
- Detailed pretreatment quality assurance checks (10 CFR 35.27, 10 CFR 35.610);
- Safe handling (when applicable) of the patient's dishes, linens, excretions (saliva, urine, feces), and surgical dressings that are potentially contaminated or that may contain radioactive sources (10 CFR 35.310, 10 CFR 35.410);

- Patient control procedures (10 CFR 35.310, 10 CFR 35.410, 10 CFR 35.610);
- Visitor control procedures, such as visitors' stay times and safe lines in radiation control areas (patient's room) (10 CFR 35.310, 10 CFR 35.410, 10 CFR 35.610);
- Licensee's WD Procedures, to ensure that each administration is in accordance with the WD, patient identity is verified, and where applicable, attention is paid to correct positioning of sources and applicators to ensure that treatment is to the correct site (or, for GSR, correct positioning of the helmet) (10 CFR 35.41);
- Proper use of safety devices and shielding to include safe handling and shielding of dislodged sources (or, in the case of remote afterloaders, disconnected sources) (10 CFR 35.410, 10 CFR 35.610);
- Size and appearance of different types of sources and applicators (10 CFR 35.410, 10 CFR 35.610);
- Previous incidents, events, and/or accidents (10 CFR 35.310, 10 CFR 35.410, 10 CFR 35.610);
- For remote afterloaders, teletherapy units, and GSR units; initial training provided by the device manufacturer or by individuals certified by the device manufacturer that is device model-specific and includes:
  - — Design, use, and function of the device, including safety systems and interpretation of various error codes and conditions, displays, indicators, and alarms;
  - — Hands-on training in actual operation of the device under the direct supervision of an experienced user including "dry runs" (using dummy sources) of routine patient set-up and treatment and implementation of the licensee's emergency procedures;
  - — A method of determining each trainee's competency to use the device for each type of proposed use, such as practical examinations.

Additional Training for Authorized Medical Physicists

In addition to the training and experience requirements of 10 CFR 35.51, we will verify that the AMP has specific training and experience in performing the measurements and calculations associated with the specific type of therapy treatments that we are requesting (e.g, manual brachytherapy, remote afterloader therapy, teletherapy, GSR therapy) and that the training involved the use of the treatment planning system that will be used for therapy at our facility.

Additional Training for Therapy Authorized Users

In addition to the training and experience requirements of 10 CFR 35.390, 10 CFR 35.394, 10 CFR 35.490, 10 CFR 35.491, and 10 CFR 35.690, we will verify that the therapy physician has specific training and experience in performing the specific therapy treatment that we are requesting, including training in the treatment planning system, quality control system, and clinical procedures that will be used at our facility.

Training for Contractors

We will ensure that individuals who work under a contractual arrangement are instructed in the topics described above, equivalent to instruction given to facility employees, and commensurate with their duties.

Training for Ancillary Staff

For the purposes of this section, ancillary staff includes personnel engaged in housekeeping, dietary services, laboratory services, security, and custodial services.

For individuals whose assigned activities during normal and abnormal situations are likely to result in a dose in excess of 1 mSv (100 mrem), we will provide instruction commensurate with potential radiological health protection problems present in the work place. Alternatively, we may choose to prohibit ancillary personnel from entering restricted or controlled areas unless escorted by trained personnel. Topics of instruction will include the following:

- Storage, transfer, or use of radiation and/or radioactive material (10 CFR 19.12);
- Health protection problems associated with exposure to radiation and/or radioactive material, precautions or procedures to minimize exposure, and the purposes and functions of protective devices (e.g., basic radiation protection concepts of time, distance, and shielding) (10 CFR 19.12);
- The applicable provisions of NRC regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material (e.g., posting and labeling of radioactive material) (10 CFR 19.12);
- Responsibility to report promptly to the licensee any condition that may lead to or cause a violation of NRC regulations and licenses or unnecessary exposure to radiation and/or radioactive material (e.g., notification of the RSO regarding radiation protection issues) (10 CFR 19.12);

- Appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and/or radioactive material (10 CFR 19.12);
- Radiation exposure reports that workers may request, as per 10 CFR 19.13 (10 CFR 19.12).

Appendix I

Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program

Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program

Facilities and Equipment

- To reduce doses received by individuals not calibrating instruments, calibrations should be conducted in an isolated area of the facility or at times when no one else is present.
- Individuals conducting calibrations will wear assigned dosimetry, if required.

Equipment Selection

- Low-energy beta emitters, such as carbon-14 and sulfur-35, are difficult to detect with Geiger-Mueller (GM) probes. The detection efficiency generally is about 2% for low-energy beta emitters. The proper surveying method (e.g., speed and height above surface) is important to perform adequate surveys. Additionally, wipes should be taken and counted on a liquid scintillation counter to verify potential contamination.
- Medium- to high-energy beta emitters, such as P-32 and Ca-45, can be detected with a pancake GM. The efficiency ranges from 15% to 40%, depending on the beta energy.
- Low-energy gamma emitters, such as I-125, can be detected with a sodium iodide (NaI) probe or a thin window GM probe (pancake or thin end-window). If the sodium iodide probe possesses a thin window and thin crystal, the detection efficiency is approximately 20%. If a pancake or thin end-window GM probe is used, the detection efficiency is significantly lower, and care should be taken to ensure that the GM probe is capable of detecting the trigger levels.
- Medium- to high-energy gamma emitters, such as I-131, can be detected with either GM or sodium iodide probes, depending on the required sensitivity. In general, the sensitivity of GM probes is much lower than for sodium iodide probes.
- The following table (except for items marked with a *), extracted from "The Health Physics & Radiological Health Handbook," Revised Edition, 1992, may be helpful in selecting instruments:

Table I.1 Typical Survey Instruments.

Portable Instruments Used for Contamination and Ambient Radiation Surveys			
Detectors	**Radiation**	**Energy Range**	**Efficiency**
Exposure Rate Meters	Gamma, X-ray	mR-R	N/A
Count Rate Meters			
GM	Alpha	All energies (dependent on window thickness)	Moderate
	Beta	All energies (dependent on window thickness)	Moderate
	Gamma	All energies	< 1%
NaI Scintillator	Gamma	All energies (dependent on crystal thickness)	Moderate
Plastic Scintillator	Beta	C-14 or higher (dependent on window thickness)	Moderate

Stationary Instruments Used to Measure Wipe, Bioassay, and Effluent Samples			
Detectors	**Radiation**	**Energy Range**	**Efficiency**
Liquid Scintillation Counter*	Alpha	All energies	High
	Beta	All energies	High
	Gamma		Moderate
Gamma Counter (NaI)*	Gamma	All energies	High
Gas Proportional	Alpha	All energies	High
	Beta	All energies	Moderate
	Gamma	All energies	< 1%

Model Procedure for Calibrating Survey Instruments

This model provides acceptable procedures for survey instrument calibrations. You may either adopt these model procedures or develop your own procedures to meet the requirements of 10 CFR 20.1101 and 10 CFR 35.61. (Detailed information about survey instrument calibration may be obtained by referring to ANSI N323A-1997, "Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments." Copies may be obtained from the American National Standards Institute at 1430 Broadway, New York, NY 10018 or by ordering electronically from <http://www.ansi.org>.

We will implement the following procedure when calibrating survey instruments:

- Radiation survey instruments will be calibrated with a radioactive source in accordance with 10 CFR 35.61. Electronic calibrations alone are not acceptable. Survey meters must be calibrated at least annually, before first use and after servicing. (Battery changes are not considered "servicing.") Instruments used to monitor higher energies are most easily calibrated in known radiation fields produced by sources of gamma rays of approximately the same energies as those to be measured. An ideal calibration source would emit the applicable radiation (e.g., alpha, beta, or gamma) with an energy spectrum similar to that to be measured and have a suitably long half-life.
- A radioactive sealed source(s) used for calibrating survey instruments will:
  - — Approximate a point source;
  - — Have its apparent source activity or the exposure rate at a given distance traceable by documented measurements to a standard certified to be within ± 5% accuracy by NIST;
  - — Emit the type of radiation measured;
  - — Approximate the same energy (e.g., Cs-137, Co-60) as the environment in which the calibrated device will be employed;
  - — Provide a radiation dose rate sufficient to reach the full scale (<1000 mR/hr) of the instrument calibrated.
- The inverse square and radioactive decay law must be used to correct changes in exposure rate due to changes in distance or source decay.
- A record must be made of each survey meter calibration and retained for 3 years after each record is made (10 CFR 20.2103(a) and 10 CFR 35.2061).
- A daily operational check, including a battery check and calibration check (with a dedicated check source), will be conducted each day of survey instrument use.

- Instrument readings should be within ± 10% of known radiation values at calibrated points; however, readings within ± 20% will be acceptable if a calibration chart or graph is prepared and made available with the instrument.
- The kinds of scales frequently used on radiation survey meters are calibrated as follows:
  - — Linear Readout Instruments must be calibrated at no fewer than two points on each scale. Calibration will be checked near the ends of each scale (at approximately 20% and 80%).
  - — Logarithmic Readout Instruments must be calibrated at one point (the midpoint) on each decade.
  - — Digital Readout Instruments with either manual or automatic scale switching for indicating exposure rates must be calibrated at no fewer than two points on each scale. Calibration will be checked near the ends of each scale (at approximately 20% and 80% of each scale).
  - — Digital readout instruments without scale switching for indicating exposure rates must be calibrated at one point (the midpoint) on each decade.
  - — Integrating instruments must be calibrated at two dose rates (at approximately 20% and 80% of the dose rate range).
- Readings above 1000 mR/hr (250 microcoulombs/kilogram of air per hour) need not be calibrated; however, such scales may be checked for operation and approximately correct response.
- Survey meter calibration records will indicate the procedure used and the data obtained. The description of the calibration will include:
  - — A description of the instrument, including the manufacturer's name, model number, serial number, and type of detector;
  - — A description of the NIST-traceable calibration source, including the calibration procedure and the exposure rate at a specified distance on a specified date;
  - — For each calibration point, the calculated exposure rate, the indicated exposure rate, the deduced correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument;
  - — The exposure reading indicated with the instrument in the "battery check" mode (if available on the instrument);
  - — For instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular);
  - — For instruments with internal detectors, the angle between the radiation flux field and a specified surface of the instrument;
  - — For detectors with removable shielding, an indication of whether the shielding was in place or removed during the calibration procedure;

  - — The exposure rate from a check source, if used;
  - — The name of the person who performed the calibration and the date it was performed.
- The following information will be attached to the instrument as a calibration sticker or tag:
  - — The source that was used to calibrate the instrument;
  - — The proper deflection in the battery check mode (unless this is clearly indicated on the instrument);
  - — Special use conditions (e.g., an indication that a scale or decade was checked only for function but not calibrated);
  - — The date of calibration and the next calibration due date;
  - — The apparent exposure rate from the check source, if used.

Calculating the Efficiency of the NaI(Tl) Uptake Probe

The sodium iodide (thallium doped) [NaI(Tl)] uptake probe is commonly used for bioassays of personnel administering I-131 radionuclides in the form of sodium iodide. RG 8.20 gives the details of bioassay requirements for I-131 radionuclides. Appendix B to Part 20 considers the Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of radionuclides for occupational exposure. Converting counts per minute (cpm) to disintegrations per minute (dpm) in determination of accurate bioassay values is important in determining thyroid burdens with radioiodine. We will calculate the efficiency of nuclear counting systems on an annual basis, before first use, and/or after repair, using the following procedure:

- Check the instrument's counting efficiency using either a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards will be within ± 5% of the stated value and traceable to a primary radiation standard such as those maintained by NIST.
- Calculate efficiency of the instrument.

  For example: $\frac{\text{(cpm from std) - (cpm from bkg)}}{\text{activity of std in microcuries}}$ = absolute efficiency[1] in cpm/microcurie

  where: cpm = counts per minute
  std = standard
  bkg = background

[1] *The absolute efficiency is dependent on the counting geometry. Applicants may elect to use the intrinsic efficiency, which no longer includes the solid angle subtended by the detector and has much less of a dependence on the counting geometry.*

In addition, a daily operational check, including a calibration check (with a dedicated check source), will be conducted each day of instrument use.

The date of the efficiency test will be attached to the instrument as a calibration sticker or tag and the following information should be included:

- The date of the next efficiency due;
- Results of efficiency calculation(s).

Calculating the Gamma Well Efficiency of Counting Equipment

Gamma well counting equipment is often used for assaying the wipe testing of packages, sealed sources, and areas where unsealed byproduct material is prepared, administered, or stored. Converting cpm to dpm using smear wipes is required when dealing with radiation surveys of sealed and unsealed radioactive materials. We will calculate the efficiency of all instruments used for assaying wipe tests on an annual basis, before first use, and/or after repair, using the following procedure:

- Check the instrument's counting efficiency, using either a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards will be within ± 5% of the stated value and traceable to a primary radiation standard such as those maintained by NIST.
- Calculate efficiency of the instrument.

  For example: $\frac{\text{[(cpm from std) - (cpm from bkg)]}}{\text{activity of std in microcuries}}$ = efficiency in cpm/microcurie

  where: cpm = counts per minute
  std = standard
  bkg = background

In addition, a daily operational check, including a calibration check (with a dedicated check source), will be conducted each day of instrument use.

The date of the efficiency test will be attached to the instrument as a calibration sticker or tag and the following information should be included:

- The date of the next efficiency due;
- Results of efficiency calculation(s).

Reference: Draft RG FC 413-4, "Guide for the Preparation of Applications for Licenses for the Use of Radioactive Materials in Calibrating Radiation Survey and Monitoring Instruments," dated June 1985.

Appendix J

Model Procedures for Dose Calibrator Calibration

Model Procedures for Dose Calibrator Calibration

Model Procedures for Testing Dose Calibrators Used to Measure Photon-Emitting Radionuclides

This model provides acceptable procedures for dose calibrator calibration. You may either adopt this model procedure or develop your own procedure to meet the requirements of 10 CFR 35.41, 10 CFR 35.60, and 10 CFR 35.63.

We will test for the following at the indicated frequency. We will repair or replace the dose calibrator if the accuracy or constancy error exceeds 10% and mathematically correct dosage readings [for dosages greater than 1.11 MBq (30 μCi)] if the geometry or linearity error exceeds 10%. We will record, for all tests, the name of the individual who performed the test.

- Constancy, at least once each day prior to assay of patient dosages (±10%);
- Linearity, at installation and at least annually thereafter (±10%);
- Geometry dependence, at installation (±10%);
- Accuracy, at installation and at least annually thereafter (±10%).

After repair, adjustment, or relocation to another building of the dose calibrator, we will repeat the above tests before use.

Constancy means reproducibility in measuring a constant source over a long period of time. We will assay with a relatively long-lived dedicated check source such as Cs-137, Co-60, cobalt-57 (Co-57)[1], or radium-226 (Ra-226)[1] using a reproducible geometry each day before using the calibrator.

We will use the following procedure:

1. Assay each reference source using the appropriate dose calibrator setting (e.g., use the Cs-137 setting to assay Cs-137);
2. Measure background at the same setting, and subtract or confirm the proper operation of the automatic background subtract circuit if it is used;
3. For each source used, record (e.g., plot, log, etc.) the activity measured, the model and serial number of the instrument, the identity of the radionuclide contained in the check source, and the date of the check;

---

[1] Co-57 and Ra-226 are not subject to NRC licensing; the appropriate State agency should be consulted to determine its requirements for possessing this material.

4. Using one of the sources, repeat the above procedure for all commonly used radionuclide settings and record (e.g., plot, log, etc.) the results;
5. Notify the RSO or the AU if the test results fall outside ±10% of the expected results.

Linearity means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. The linearity of a dose calibrator will be ascertained over the range of its use between the maximum activity administered and 1.1 MBq (30 μCi). This test will be done using a vial or syringe of technetium-99m (Tc-99m) whose activity is at least as large as the maximum activity normally assayed for administration. Two methods are described below – the time decay method and the shield method. The shield method confirms activity linearity in establishing reproducible ratios between displayed readings and tube calibration factors.

Time Decay Method

We will use the following procedure:

1. Assay the Tc-99m syringe or vial in the dose calibrator, measure the background, and calculate the net activity in millicuries; record the date, time to the nearest minute, and net activity on the dose calibrator linearity test form.
2. Repeat the assay at approximately 4-hour intervals during the workday, continuing on subsequent days until the assayed activity is less than 1.1 MBq (30 μCi), and for dose calibrators on which a range is selected with a switch, selecting the range normally used for the measurement.
3. Convert the time and date information recorded to hours elapsed since the first assay.
4. Record the measured activities, the calculated activities, the time elapsed between measurements, the model number and serial number of the dose calibrator, and the date(s) of the test.
5. Notify the RSO if the worst deviation is more than ±10%.

Shield Method

If we decide to use a set of "sleeves" of various thicknesses to test for linearity, it will first be necessary to calibrate the sleeves.

We will use the following procedure:

Note: The applicant should review the procedure for calibrating sleeves against the manufacturer's instructions. Some sleeve manufacturers' procedures indicate that various sleeves must be stacked to achieve a desired attenuation, while some procedures indicate that a given sleeve must be replaced with the next sleeve.

1. Begin the linearity test as described in the decay method described above. After making the first assay, the sleeves can be calibrated as follows. Steps 2 through 4 below must be completed within 6 minutes (i.e., approximately 1% of decay of Tc-99m).
2. Put the base in the dose calibrator with the Tc-99m. Record the indicated activity. Record the source geometry.
3. Add sleeve 1. Record the sleeve number and indicated activity.
4. Continue for all sleeves and/or combinations of sleeves.
5. Complete the decay method linearity test steps 2 through 5 above and confirm that the readings are linear.
6. From the data recorded above, determine the ratio of the reading in step 2 (base only) to the reading in step 3 (sleeve 1). This is the ratio for sleeve 1.
7. Continue for the other sleeves and/or combinations of sleeves by determining the ratio of the reading in step 2 to each of the readings in step 4. The ratio for sleeve x is the reading from the base only (step 2) divided by the reading from sleeve x. ***Note:*** The ratio for the base is 1.00.
8. The table of sleeve numbers and ratios constitutes the calibration of the sleeve set.

The sleeve set may now be used to test dose calibrators for linearity.

1. Use the same source geometry as was used to initially calibrate the sleeves.
2. Steps 3 through 5 below must be completed within 6 minutes.
3. Put the base in the dose calibrator with the Tc-99m. Record the indicated activity.
4. Add sleeve 1. Record the sleeve number and indicated activity.
5. Continue for all sleeves and/or combinations of sleeves.
6. Multiply the reading obtained with each sleeve (or combination of sleeves) by the ratio for that sleeve (or combination of sleeves). For example, multiply the reading obtained with sleeve 2 by the ratio for sleeve 2. Determine the calculated value for each sleeve (or combination of sleeves).
7. Determine the average of the set of calculated values. Determine the deviation of each calculated value from the average.
8. Record the measured activities, the calculated values, the time elapsed between the first and last measurement, the model number and serial number of the dose calibrator and sleeve set, and the date(s) of the test.
9. Notify the RSO if the worst deviation is more than ±10%.

Geometry independence means that the indicated activity does not change with volume or configuration. The test for geometry independence will be conducted using syringes and vials that are representative of the entire range of size, shape, and constructions normally used for injections and a vial similar in size, shape, and construction to the generator and radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3-centimeter cubed (cc) plastic syringes and that radiopharmaceutical kits are made in 30-cc glass vials and your predetermined safety margin is ±10%.

Note: If you do not use these volumes, the procedure should be changed so that the syringes and vials are tested throughout the range of volumes commonly used. Additionally, if gamma-emitting radionuclides are used with energies significantly different from Tc-99m or beta-emitting radionuclides used, the following procedure must be repeated for those radionuclides.

We will use the following procedure:

1. In a small beaker or vial, mix 2 cc of a solution of Tc-99m with an activity concentration between 1 and 10 mCi/milliliter (ml). Set out a second small beaker or vial with water.
2. To test the geometry dependence for a 3-cc syringe, draw 0.5 cc of the Tc-99m solution into the syringe and assay it. Record the volume and activity (e.g., mCi) indicated.
3. Remove the syringe from the calibrator, draw an additional 0.5 cc of water, and assay again. Record the volume and activity indicated.
4. Repeat the process until you have assayed a 2.0-cc volume.
5. Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard activity by the activity indicated for each volume. The quotient is a volume correction factor. Alternately, you may graph the data and draw horizontal 10% error lines above and below the chosen "standard volume."
6. Record the model and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, and the date of the test.
7. Notify the RSO if any correction factors are greater than 1.1 or less than 0.9, or if any data points lie outside the ± 10% error lines.
8. To test the geometry dependence for a 30-cc glass vial, draw 1.0 cc of the Tc-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and activity indicated.
9. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of water, and assay again. Record the volume and activity indicated.
10. Repeat the process until you have assayed a 19.0-cc volume. The entire process must be completed within 10 minutes.

11. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all the other volumes, divide the standard activity by the activity indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 10% error lines above and below the chosen "standard volume."
12. Record the model and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, and the date of the test.
13. Notify the RSO if any correction factors are greater than 1.1 or less than 0.9, or if any data points lie outside the ± 10% error lines.

Accuracy means that, for a given calibrated reference source, the indicated activity (e.g., mCi) value is equal to the activity value determined by NIST or by the supplier who has compared that source to a source that was calibrated by NIST, corrected for decay. Certified sources are available from NIST and from many radionuclide suppliers.

We will use the following procedure:

1. Assay a calibrated reference source at the appropriate settings (i.e., use the Co-57 setting to assay Co-57), and then remove the source and measure the background. Record the net activity.
2. Repeat the procedure for any other calibrated reference sources possessed.
3. Record the model and serial number of the dose calibrator, the model and serial number of each source used, the identity of the radionuclide contained in the source and its activity, the date of the test, and the results of the test.
4. Notify the RSO if the test results do not agree, within ±10%, with the certified value of the reference source(s).
5. At the same time the accuracy test is done, assay the source that will be used for the daily constancy test (it need not be a certified reference source) on all commonly used radionuclide settings.

We will, through the RSO, ensure that the operation of the dose calibrator is in accordance with approved procedures and regulatory requirements.

Appendix K

Suggested Medical Licensee Audit

Suggested Medical Licensee Audit

Annual Radiation Protection Medical Licensee Audit

Note: All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit. For example, licensees do not need to address areas which do not apply to the licensee's activities, and activities that have not occurred since the last audit need not be reviewed at the next audit.

Date of This Audit: _____ Date of Last Audit: _____

Next Audit Date: _____

Auditor: _____ Date: _____
(Signature)

Management Review: _____ Date: _____
(Signature)

Audit History

A. Were previous audits conducted annually [20.1101]?

B. Were records of previous audits maintained [20.2102]?

C. Were any deficiencies identified during previous audit?

D. Were corrective actions taken? (Look for repeated deficiencies).

Organization and Scope of Program

A. Radiation Safety Officer:

   1. If the RSO was changed, was license amended [35.13]?
   2. Does new RSO meet NRC training requirements [35.50, 35.57, 35.59]?
   3. Is RSO fulfilling his/her duties [35.24]?

B. Multiple places of use? If yes, list locations.

C. Are all locations listed on license? [L/C]

D. Were annual audits performed at each location [20.1101]? If no, explain.

E. Describe scope of the program (staff size, number of procedures performed, etc.).

F. Licensed Material:

1. Isotope, chemical form, quantity and use as authorized [L/C]?
2. Does the total amount of radioactive material possessed require financial assurance [30.35(a)]? If so, is financial assurance adequate?
3. Calibration, transmission, and reference sources [35.65]?
    a. Sealed sources manufactured and distributed by a person licensed pursuant to 10 CFR 32.74, equivalent Agreement State regulations, or redistributed by a licensee authorized to redistribute sealed sources, and sources do not exceed 30 millicuries each [35.65(a) and (b)]?
    b. Any byproduct material with a half-life not longer than 120 days in individual amounts not to exceed 15 millicuries [35.65(c)]?
    c. Any byproduct material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 200 microcuries or 10E3 times the quantities in Appendix B of Part 30 [35.65(d)]?
    d. Technetium-99m in individual amounts as needed [35.65(e)]?
4. Unsealed materials used under 35.100, 200, and 300 are:
    a. Obtained from a manufacturer or properly licensed organization [32.72]?

AND/OR

    b. Prepared by a physician authorized user, an authorized nuclear pharmacist, or an individual under the supervision of an authorized nuclear pharmacist or physician authorized user?

AND/OR

    c. Obtained and prepared for research in accordance with 10 CFR 35.100, 10 CFR 35.200, and 10 CFR 35.300, as applicable?

G. Are the sealed sources possessed and used as described in the Sealed Source and Device Registration (SSDR) Certificate? Are copies of (or access to) SSDR Certificates possessed? Are manufacturers' manuals for operation and maintenance of medical devices possessed? [32.210, 35.400, 35.500, 35.600]?

H. Are the actual uses of medical devices consistent with the authorized uses listed on the license?

I. If places of use changed, was the license amended [35.13(e)]?

J. If control of license was transferred or bankruptcy filed, was NRC prior consent obtained or notification made, respectively [30.34(b)]?

Radiation Safety Program

A. Minor changes to program [35.26]?

B. Records of changes maintained for 5 years [35.2026]?

C. Content and implementation reviewed annually by the licensee [20.1101(c)]?

D. Records of reviews maintained [20.2102]?

Use by Authorized Individuals [L/C]

Compliance is established by meeting at least one criterion under each category.

A. Authorized Nuclear Pharmacist [35.55, 35.57, 35.59] (***Note:*** Does Not Apply to Facilities That Are Registered/Licensed by FDA/State Agency as a Drug Manufacturer with Distribution Regulated Under Part 32):

_____ 1. Certified by specialty board

_____ 2. Identified on NRC or Agreement State license

_____ 3. Identified on permit issued by broad scope or master materials licensee

_____ 4. Listed on facility license

B. Authorized User [35.57, 35.59, and 35.190, 35.290, 35.390, 35.392, 35.394, 35.490, 35.491, 35.590, 35.690]:

_____ 1. Certified by specialty board

_____ 2. Identified on NRC or Agreement State license

_____ 3. Identified on permit issued by broad scope or master materials licensee

_____ 4. Listed on facility license

C. Authorized Medical Physicist [35.51, 35.57, 35.59]:

_____ 1. Certified by specialty board

_____ 2. Identified on NRC or Agreement State license

_____ 3. Identified on permit issued by broad scope or master materials licensee

_____ 4. Listed on facility license

Mobile Service

A. Operates services per 35.80, 35.647?

B. Compliance with 20.1301 evaluated and met?

C. Letter signed by management of each client [35.80(a)]?

D. Licensed material was not delivered to client's address (unless client was authorized) [35.80(b)]?

E. Dosage measuring instruments checked for proper function before used at each address of use or on each day of use, if more frequent [35.80(a)]?

F. Survey instruments checked for proper operation before used at each address of use [35.80(a)]?

G. Survey of all areas of use prior to leaving each client address [35.80(a)]?

H. Additional technical requirements for mobile remote afterloaders per [35.647]?

Amendments Since Last Inspection [35.13]

A. Any Amendments since last inspection [35.13]?

Notifications Since Last Inspection [35.14]

A. Any Notifications since last inspection [35.14]?

B. Appropriate documentation provided to NRC for authorized nuclear pharmacist, authorized medical physicists, or authorized user no later than 30 days after the individual starts work [35.14(a)]?

C. NRC notified within 30 days after: authorized user, authorized nuclear pharmacist, authorized medical physicist, or RSO stops work or changes name; licensee's mailing address changes; licensee's name changes without a transfer of control of the license; or licensee has added to or changed an area of use for 35.100 or 35.200 use [35.14(b)]?

Training, Retraining, And Instructions to Workers

A. Have workers been provided with required instructions [19.12, 35.27, 35.310, 35.410, 35.610]?

B. Is the individual's understanding of current procedures and regulations adequate?

C. Training program implemented?

1. Operating procedures [35.27, 35.310, 35.410, 35.610]?
2. Emergency procedures [35.27, 35.310, 35.410, 35.610]?
3. Periodic training required and implemented [35.310, 35.410, 35.610]?
4. Were all workers who are likely to exceed 1 mSv (100 mrem) in a year instructed and was refresher training provided, as needed [10 CFR 19.12]?
5. Was each supervised user instructed in preparation of material, principles, and procedures for radiation safety, device usage, and administration of written directives, as appropriate [35.27]?
6. Are initial and periodic training records maintained for each individual [35.2310]?
7. Briefly describe training program:

D. Additional therapy device instructions/training:

1. Unit operation, inspection, associated equipment, survey instruments [35.610]?
2. License conditions applicable to the use of the unit?
3. Emergency drills [35.610]?

E. Part 20 – Workers cognizant of requirements for:

1. Radiation Safety Program [35.24, 35.26, 20.1101]?
2. Annual dose limits [20.1201, 20.1301, 20.1302]?
3. NRC Forms 4 and 5?
4. 10% monitoring threshold [20.1502]?
5. Dose limits to embryo/fetus and declared pregnant worker [20.1208]?
6. Grave Danger Posting [20.1902(c)]?
7. Procedures for opening packages [20.1906]?

F. Supervision of individuals by authorized user and/or authorized nuclear pharmacist in accordance with 10 CFR 35.27?

Manual Brachytherapy And Unsealed Therapy Training

A. Safety instruction to personnel provided include [10 CFR 35.310, 10 CFR 35.410]:
   1. Control of patient and visitors?
   2. Routine visitation to patients in accordance with 10 CFR 20.1301?
   3. Contamination control and size/appearance of sources?
   4. Safe handling and shielding instructions?
   5. Waste control?
   6. RSO and AU notification in emergency or death?
   7. Records retained [35.2310]?

Facilities

A. Facilities as described in license application?

B. Therapy device facilities provided with electrical interlock system, viewing and intercom systems, radiation monitor, source retraction mechanism, and source indicator lights [35.615, 20.1601]?

C. Emergency source recovery equipment available [35.415, 35.615]?

D. Storage areas:
   1. Materials secured from unauthorized removal or access [20.1801]?
   2. Licensee controls and maintains constant surveillance of licensed material not in storage [20.1802]?

E. Therapy unit operation:
   1. Unit, console, console keys, and treatment room controlled adequately [20.1801, 35.610(a)(1)]?
   2. Restricted to certain source orientations and/or gantry angles [L/C]?
   3. Ceases to operate in restricted orientation(s) [L/C]?
   4. Only one radiation device can be placed in operation at a time within the treatment room [35.610(a)(3)]?

Dose or Dosage Measuring Equipment

A. Possession, use, calibration, and check of instruments to measure activities of unsealed radionuclides [10 CFR 35.60]:

1. List type of equipment used:
2. Approved procedures for use of instrumentation followed?
3. Constancy, accuracy, linearity, and geometry dependence tests performed in accordance with nationally recognized standards or the manufacturer's instructions?
4. Instrument repaired or replaced or dosages mathematically corrected, as required, when tests do not meet the performance objectives provided in the nationally recognized standard or manufacturer's instructions (e.g., ±10%)?
5. Records maintained and include required information [10 CFR 35.2060]?

B. Determination of dosages of unsealed byproduct material [35.63]?

1. Each dosage determined and recorded prior to medical use [35.63(a)]?
2. Measurement of unit dosages made either by direct measurement or by decay correction [35.63(b)]?
3. For other than unit dosages, measurement made by direct measurement of radioactivity or by combination of radioactivity or volumetric measurement and calculation [35.63(c)]?

C. Licensee uses generators?

1. First eluate after receipt tested for Mo-99 breakthrough [35.204(b)]?
2. No radiopharmaceuticals *administered* with Mo-99 concentrations over 0.15 μCi per mCi of Tc-99m [35.204(a)]?
3. Records maintained [35.2204]?

D. Dosimetry Equipment [35.630]:

1. Calibrated system available for use [35.630(a)]?
2. Calibrated by NIST or an AAPM-accredited lab within previous 2 years and after servicing [35.630(a)(1)] OR calibrated by intercomparison per 35.630(a)(2)?
3. Calibrated within the previous 4 years [35.630(a)(2)]?
4. Licensee has available for use a dosimetry system for spot-check measurements [35.630(b)]?
5. Record of each calibration, intercomparison, and comparison maintained [35.2630]?

Radiation Protection And Control of Radioactive Material

A. Use of radiopharmaceuticals:

1. Protective clothing worn?
2. Personnel routinely monitor their hands?
3. No eating/drinking in use/storage areas?
4. No food, drink, or personal effects kept in use/storage areas?
5. Proper dosimetry worn?
6. Radioactive waste disposed of in proper receptacles?
7. Syringe shields and vial shields used?

B. Leak tests and Inventories:

1. Leak test performed on sealed sources and brachytherapy sources [35.67(b)(1)]?
2. Inventory of sealed sources and brachytherapy sources performed semiannually [35.67(g)]?
3. Records maintained [35.2067]?

Radiation Survey Instruments

A. Survey instruments used to show compliance with Part 20 and 30.33(a)(2):

1. Appropriate operable survey instruments possessed or available [10 CFR Part 20]?
2. Calibrations [35.61(a) and (b)]:
   a. Before first use, annually and after repairs?
   b. Within 20% on each scale or decade of interest?
3. Records maintained [35.2061]?

B. Radiation surveys performed in accordance with the licensee's procedures and the regulatory requirements [20.1501, 35.70]?

1. Daily in all areas where radiopharmaceuticals requiring a written directive are prepared or administered (except patient rooms) [35.70]?
2. Weekly in all areas where radiopharmaceuticals or waste is stored?

3. Weekly wipes in all areas where radiopharmaceuticals are routinely prepared, administered, or stored?
4. Trigger levels established?
5. Corrective action taken and documented if trigger level exceeded?
6. Techniques can detect 0.1 mR/hr, 2000dpm?
7. Surveys made to assure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the sources(s) in the shielded position does not exceed the levels stated in the Sealed Source and Device Registry [35.652(a)] and records maintained [35.2652]?
    a. After new source installation?
    b. Following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical mechanism that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s)?

Public Dose

A. Is licensed material used in a manner to keep doses below 1mSv (100 mrem) in a year [10 CFR 20.1301(a)(1)]?

B. Has a survey or evaluation been performed per 10 CFR 20.1501(a)?

C. Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation?

D. Do unrestricted area radiation levels exceed 0.02 mSv (2 mrem) in any one hour [10 CFR 20.1301(a)(2)]?

E. Is licensed material used or stored in a manner that would prevent unauthorized access or removal [10 CFR 20.1801]?

F. Records maintained [10 CFR 20.2103, 10 CFR 20.2107]?

Patient Release

A. Individuals released when TEDE less than 0.5 rem [35.75(a)]?

B. Instructions to the released individual, including breast-feeding women, include required information [35.75(b)]?

C. Release records maintained [35.2075(a)]?

D. Records of instructions given to breast-feeding women maintained, if required [35.2075(b)]?

Radiopharmaceutical Therapy

A. Safety precautions implemented to include patient facilities, posting, stay times, patient safety guidance, release, and contamination controls [35.315(a)]?

B. RSO and AU promptly notified if patient died or had a medical emergency [35.315(b)]?

Brachytherapy

A. Safety precautions implemented to include patient facilities, posting, stay times, and emergency response equipment [35.415]?

B. Survey immediately after implant [35.404(a)]?

C. Patients surveyed immediately after removing the last *temporary* implant source [35.404(b)]?

D. RSO and AU promptly notified if patient died or had a medical emergency [35.415(c)]?

E. Records maintained [35.2404]?

Radioactive Waste

A. Disposal:

   1. Decay-in-storage [35.92]
   2. Procedures followed [35.92]?
   3. Labels removed or defaced [20.1904, 35.92]?

B. Special procedures performed as required [L/C]?

C. Improper/unauthorized disposals [20.2001]?

D. Records maintained [20.2103(a), 20.2108, 35.2092]?

E. Effluents:

1. Release to sanitary sewer [20.2003]?
   a. Material is readily soluble or readily dispersible [20.2003(a)(1)]?
   b. Monthly average release concentrations do not exceed 10 CFR Part 20 App. B, Table 2 values?
   c. No more than 5 Ci of H-3, 1 Ci of C-14 and 1 Ci of all other radionuclides combined released in a year [20.2003]?
   d. Procedures to ensure representative sampling and analysis implemented [20.1501]?
2. Release to septic tanks [20.2003]?
   a. Within unrestricted limits [10 CFR Part 20 App. B, Table 2, Part 20]?
3. Waste incinerated?
   a. License authorizes [20.2004(a)(3)]?
   b. Directly monitor exhaust?
   c. Airborne releases evaluated and controlled [20.1302, 20.1501]?
4. Air effluents and ashes controlled [20.1101, 20.1201, 20.1301, 20.1501, 20.2001, L/C]? (See also IP 87102, RG 8.37)
   a. Air effluent less than 10 mrem constraint limit [20.1101]?
   b. If no, reported appropriate information to NRC.
      i. Corrective actions implemented and on schedule?
   c. Description of effluent program:
      i. Monitoring system hardware adequate?
      ii. Equipment calibrated, as appropriate?
      iii. Air samples/sampling technique (i.e. charcoal, HEPA, etc.) analyzed with appropriate instrumentation?

F. Waste storage

1. Protection from elements and fire?
2. Control of waste maintained [20.1801]?

3. Containers properly labeled and area properly posted [20.1902, 20.1904]?
4. Package integrity adequately maintained?

G. Waste disposal:

1. Sources transferred to authorized individuals [20.2006, 20.2001, 30.51]?
2. Name of organization: _____

H. Records of surveys and material accountability are maintained [20.2103, 20.2108, 35.2092]?

Receipt And Transfer of Radioactive Material

A. Describe how packages are received and by whom.

B. Written package opening procedures established and followed [20.1906(e)]?

C. All incoming packages with a DOT label *wiped*, unless exempted (gases and special form) [20.1906(b)(1)]?

D. Incoming packages surveyed [20.1906(b)(2)]?

E. Monitoring in (C) and (D) performed within time specified [20.1906(c)]?

F. Transfer(s) performed per [30.41]?

G. All sources surveyed before shipment and transfer [20.1501(a), 49 CFR 173.475(i)]?

H. Records of surveys and receipt/transfer maintained [20.2103(a), 30.51]?

I. Package receipt/distribution activities evaluated for compliance with 20.1301?

Transportation (10 CFR 71.5(a) and 49 CFR 171-189)

A. Shipments are:

1. delivered to common carriers;
2. transported in own private vehicle;
3. both;
4. no shipments since last audit.

B. Return radiopharmacy doses or sealed sources?

1. Licensee assumes shipping responsibility?
2. If NO, describe arrangements made between licensee and radiopharmacy for shipping responsibilities:

C. Packages:

1. Authorized packages used [173.415, 173.416]?
2. Performance test records on file?
   a. DOT-7A packages [173.415(a)]
   b. Special form sources [173.476(a)]
3. Two labels (White-I, Yellow-II, Yellow-III) with TI, Nuclide, Activity, and Hazard Class [172.403, 173.441]?
4. Properly marked (Shipping Name, UN Number, Package Type, RQ, "This End Up" (liquids), Name and Address of consignee) [172.301, 172.304, 172.310, 172.312, 172.324]?
5. Closed and sealed during transport [173.475(f)]?

D. Shipping Papers:

1. Prepared and used [172.200(a)]?
2. Proper Shipping Name, Hazard Class, UN Number, Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity, Category of Label, TI, Shipper's Name, Certification and Signature, Emergency Response Phone Number, "Limited Quantity" (if applicable), "Cargo Aircraft Only" (if applicable) [172.200-204]?
3. Readily accessible during transport [177.817(e)]?

Teletherapy And Gamma Stereotactic Radiosurgery Servicing

A. Inspection and servicing performed following source replacement or at intervals not to exceed 5 years [35.655(a)]?

B. Needed service arranged for as identified during the inspection?

C. Service performed by persons specifically authorized to do so [35.655(b)]?

Full Calibration-Therapeutic Medical Devices

A. Proper protocol(s) used (e.g., TG-21, AAPM 54, TG-56, TG-40, etc.) [35.632, 633, 635]?

B. Performed prior to first patient use [35.632(a)(1), 633(a)(1), 635(a)(1)]?

C. At intervals not to exceed one year for teletherapy, gamma stereotactic, and LDR remote afterloader; at intervals not exceeding one quarter for HDR, MDR, and PDR remote afterloaders [35.632(a)(3)], 35.633(a)(3) and (4), 35.635(a)(3)]?

D. Whenever spot-checks indicate output differs from expected by ±5% [35.632(a)(2)(i), 35.635(a)(2)(i)]?

E. After source exchange, relocation, and major repair or modification [35.632(a)(2), 35.633(a)(2), 35.635(a)(2)]?

F. Performed with properly calibrated instrument [35.632(c), 35.633(c), 35.635(c)]?

G. Includes:

1. For teletherapy:
    a. Output measured within ±3% of expected for the range of field sizes, range of distances [35.632(b)(1)]?
    b. Coincidence of radiation field and field light localizer [35.632(b)(2)]?
    c. Uniformity of radiation field and beam angle dependence [35.632(b)(3)]?
    d. Timer accuracy and linearity over the range of use [35.632(b)(4)]?
    e. On-off error [35.632(b)(5)]?
    f. Accuracy of all measuring and localization devices [35.632(b)(6)]?

2. For remote afterloaders:
    a. Output measured within ±5% of expected [35.633(b)(1)]?
    b. Source positioning accuracy within ±1 millimeter [35.633(b)(2)]?
    c. Source retraction with backup battery upon power failure [35.633(b)(3)]?
    d. Length of source transfer tubes [35.633(b)(4)]?
    e. Timer accuracy and linearity over the typical range of use [35.633(b)(5)]?
    f. Length of the applicators [35.633(b)(6)]?

g. Function of source transfer tubes, applicators, and transfer tube-applicator interfaces [35.633(b)(7)]?

h. Autoradiograph quarterly of the LDR source(s) to verify source(s) arrangement and inventory [35.633(e)]?

3. For gamma stereotactic radiosurgery:

a. Output measured within ±3% of expected [35.635(b)(1)]?

b. Helmet factors [35.635(b)(2)]?

c. Isocenter coincidence [35.635(b)(3)]?

d. Timer accuracy and linearity over the range of use [35.635(b)(4)]?

e. On-off error [35.635(b)(5)]?

f. Trunnion centricity [35.635(b)(6)]?

g. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off [35.635(b)(7)]?

h. Helmet microswitches [35.635(b)(8)]?

i. Emergency timing circuit [35.635(b)(9)]?

j. Stereotactic frames and localizing devices (trunnions) [35.635(b)(10)]?

H. Output corrected mathematically for decay [35.632(e), 35.633(g), 35.635(e)]?

I. Records maintained [35.2632]?

Periodic Spot Checks For Therapeutic Devices

A. Performed at required frequency [35.642(a), 35.643(a), 35.645(a)]?

B. Procedures established by authorized medical physicist [35.642(b), 35.643(b), 35.645(b)]?

C. Procedures followed?

D. Medical physicist reviews results within 15 days [35.642(c), 35.643(c), 35.645(b)]?

E. Performed with properly calibrated instrument [35.642(a)(5), 35.645(c)(2)(i)]?

F. Output and safety spot checks include:

1. For teletherapy:
    a. Timer accuracy and linearity over the range of use [35.642(a)(1)]?
    b. On-off error [35.642(a)(2)]?
    c. Coincidence of radiation field and field light localizer [35.642(a)(3)]?
    d. Accuracy of all measuring and localization devices [35.642(a)(4)]?
    e. The output for one typical set of operating conditions [35.642(a)(5)]?
    f. Difference between measured and expected output [35.642(a)(6)]?
    g. Interlock systems [35.642(d)(1)]?
    h. Beam stops [35.642(d)(2)]?
    i. Source exposure indicator lights [35.642(d)(3)]?
    j. Viewing and intercom systems [35.642(d)(4)]?
    k. Treatment room doors, inside and out [35.642(d)(5)]?
    l. Electrical treatment doors with power shut off [35.642(d)(6)]?

2. For remote afterloaders:
    a. Interlock systems [35.643(d)(1)]?
    b. Source exposure indicator lights [35.643(d)(2)]?
    c. Viewing and intercom systems, except for LDR [35.643(d)(3)]?
    d. Emergency response equipment [35.643(d)(4)]?
    e. Radiation monitors used to indicate source position [35.643(d)(5)]?
    f. Timer accuracy [35.643(d)(6)]?
    g. Clock (date and time) in the unit's computer [35.643(d)(7)]?
    h. Decayed source(s) activity in the unit's computer [35.643(d)(8)]?

3. For gamma stereotactic radiosurgery:
    a. Treatment table retraction mechanism [35.645(c)(1)(i)]?
    b. Helmet microswitches [35.645(c)(1)(ii)]?
    c. Emergency timing circuits [35.645(c)(1)(iii)]?
    d. Stereotactic frames and localizing devices [35.645(c)(1)(iv)]?

e. The output for one typical set of operating conditions [35.645(c)(2)(i)]?

f. Difference between measured and expected output [35.645(c)(2)(ii)]?

g. Source output compared against computer calculation of output [35.645(c)(2)(iii)]?

h. Timer accuracy and linearity over the range of use [35.645(c)(2)(iv)]?

i. On-off error [35.645(c)(2)(v)]?

j. Trunnion centricity [35.645(c)(2)(vi)]?

k. Interlock systems [35.645(d)(1)]?

l. Source exposure indicator lights [35.645(d)(2)]?

m. Viewing and intercom systems [35.645(d)(3)]?

n. Timer termination [35.645(d)(4)]?

o. Radiation monitors used to indicate room exposures [35.645(d)(5)]?

p. Emergency off buttons [35.645(d)(6)]?

G. Licensee promptly repaired items found to be not operating properly and did not use unit until repaired, if required [35.642(e), 35.643(e), 35.645(f)]?

H. Records maintained [35.2642, 35.2643, 35.2645]?

Installation, Maintenance, and Repair of Therapy Devices

A. Only authorized individuals perform installation, maintenance, adjustment, repair, and inspection [35.605, 35.655]? Name of organization/individual:_____

B. Records maintained [35.2605, 35.2655]?

Operating Procedures For Therapy Devices

A. Instructions on location of emergency procedures and emergency response telephone numbers are posted at the device console [35.610(c)]?

B. Copy of the entire procedures physically located at the device console [35.610(b)]?

C. Procedures include:

1. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions [35.610(a)(4)]?
2. The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure [35.610(a)(4)]?
3. The names and telephone numbers of the authorized users, the authorized medical physicist, and the RSO to be contacted if the unit or console operates abnormally [35.610(a)(4)]?

D. Radiation survey of patient is performed to ensure source is returned to shielded position [35.604(a)]?

E. Records of radiation surveys maintained for 3 years [35.2404]?

F. Authorized medical physicist and authorized user:

1. Physically present during initiation of patient treatment with remote afterloaders (***Note:*** for MDR and PDR, an appropriately trained physician under the supervision of the authorized user may be physically present instead of the authorized user) [35.615(f)(1) and (2)]?
2. Physically present throughout all patient treatments with a gamma stereotactic radiosurgery device [35.615(f)(3)]?

Personnel Radiation Protection

A. Exposure evaluation performed [20.1501]?

B. ALARA program implemented [20.1101(b)]?

C. External Dosimetry:

1. Monitors workers per [20.1502(a)]?
2. External exposures account for contributions from airborne activity [20.1203]?
3. Supplier _____ Frequency _____
4. Supplier is NVLAP-approved [20.1501(c)]?
5. Dosimeters exchanged at required frequency?

D. Internal Dosimetry

1. Monitors workers per 20.1502?
2. Briefly describe program for monitoring and controlling internal exposures [20.1701, 20.1702]?
3. Monitoring/controlling program implemented (includes bioassays)?
4. Respiratory protection equipment [20.1703]?

E. Reports

1. Reviewed by _____ Frequency _____
2. Auditor reviewed personnel monitoring records for period _____ to _____
3. Prior dose determined for individuals likely to receive doses [20.2104]?
4. Maximum exposures TEDE _____ Other _____
5. Maximum CDEs _____ Organs _____
6. Maximum CEDE _____
7. Internal and external summed [20.1202]?
8. TEDEs and TODEs within limits [20.1201]?
9. NRC forms or equivalent [20.2104(d), 20.2106(c)]?
   a. NRC-4 Complete:
   b. NRC-5 Complete:
10. Worker declared her pregnancy in writing during audit period (review records)? If yes, in compliance with [20.1208] and records maintained [20.2106(e)]?

F. Who performed any planned special exposures at this facility (number of people involved and doses received) [20.1206, 20.2104, 20.2105, 20.2204]?

G. Records of exposures, surveys, monitoring, and evaluations maintained [20.2102, 20.2103, 20.2106]?

Confirmatory Measurements

Detail location and results of confirmatory measurements.

Medical Events

If medical events [criteria in 35.3045] have occurred since the last audit, evaluate the incident(s) and procedures for implementing and administering written directives using the existing guidance.

1. Event date _____ Information Source _____

2. Notifications

NRC Ops Center	NRC Region
Referring Physician	Patient
In writing/By telephone	

If notification did not occur, why not?

3. Written Reports [35.3045]:
   a. Submitted to Region within 15 days?

Notification and Reports

A. In compliance with 19.13, 30.50 (reports to individuals, public and occupational, monitored to show compliance with Part 20)?

B. In compliance with 20.2201, 30.50 (theft or loss)?

C. In compliance with 20.2202, 30.50 (incidents)?

D. In compliance with 20.2203, 30.50 (overexposures and high radiation levels)?

E. Aware of NRC Ops Center phone number?

F. In compliance with 20.2203 (Constraint on air emissions)?

Posting and Labeling

A. NRC Form 3, "Notice to Workers" is posted [19.11]?

B. Parts 19, 20, 21, Section 206 of Energy Reorganization Act, procedures adopted pursuant to Part 21, and license documents are posted, or a notice indicating where documents can be examined is posted [19.11, 21.6]?

C. Other posting and labeling per 20.1902, 1904 and not exempted by 20.1903, 20.1905?

Recordkeeping for Decommissioning

A. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination [30.35(g)]?

B. Records include all information outlined in 10 CFR 30.35(g)?

Bulletins and Information Notices

A. Bulletins, Information Notices, NMSS Newsletters, etc., received?

B. Appropriate action in response to Bulletins, Generic Letters, etc.?

Special License Conditions or Issues

A. Special license conditions or issues to be reviewed:

B. Evaluation:

Audits and Findings

A. Summary of findings:

B. Corrective and preventive actions:

Appendix L

Model Procedures for an Occupational Dose Program

Model Procedures for an Occupational Dose Program

This model provides acceptable procedures for an external occupational dose program and references for developing an internal occupational dose program. You may either adopt these model procedures for an external occupational dose program or develop your own procedures to meet the requirements of 10 CFR 20.1101 and Subparts C and F of 10 CFR Part 20.

The mechanism by which doses to individuals from exposure to radiation are evaluated is called dosimetry. Dosimetry is required for individuals likely to receive in 1 year a dose in excess of 10% of the applicable regulatory limits in 10 CFR 20.1201. The Total Effective Dose Equivalent (TEDE) is the sum of the deep-dose equivalent (external exposure) and the committed effective dose equivalent (internal exposure). The definition of the terms TEDE, deep-dose equivalent (DDE), and committed effective dose equivalent (CEDE) can be found in 10 CFR 20.1003, "Definitions." To demonstrate that dosimetry is not required, the licensee needs to have available for inspection an evaluation to demonstrate that the workers are not likely to exceed 10% of the applicable annual limits (10 CFR 20.1501).

If an individual is likely to receive more than 10% of the annual dose limits, NRC requires the licensee to monitor the dose, to maintain records of the dose, and, on at least an annual basis, to inform the worker of his/her dose.

The As Low As Reasonably Achievable "ALARA" Program

10 CFR 20.1101 states that "each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities..." and, "the licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA)." Additionally, 10 CFR 20.1101 requires that licensees periodically review the content of the radiation protection program and its implementation.

External Dose Exposure

Dosimetry allows the licensee to ensure that doses are maintained ALARA. Dosimetry also allows the licensee to show compliance with the occupational dose limits required by NRC.

Providing for the safe use of radioactive materials and radiation is a management responsibility. It is important that management recognize the importance of radiation monitoring in the overall requirements for radiation protection.

There are three dose limits included in 10 CFR 20.1201 that apply to external exposure: deep dose to the whole body (5 rems or 0.05 Sv), shallow dose to the skin or extremities (50 rems or

0.5 Sv), and dose to the lens of the eye (15 rems or 0.15 Sv). According to the definitions in 10 CFR 20.1003, the (DDE) to the whole body is considered to be at a tissue depth of 1 cm (1000 mg/cm^2), shallow-dose equivalent to the skin or extremities at 0.007 cm (7 mg/cm^2), and eye dose equivalent at 0.3 cm (300 mg/cm^2). In evaluating the eye dose equivalent, it is acceptable to take credit for the shielding provided by protective lenses.

Monitoring an individual's external radiation exposure is required by 10 CFR 20.1502(a) if the external occupational dose is likely to exceed 10% of the dose limit appropriate for the individual (i.e., adult, minor, or the fetus of a declared pregnant woman). External radiation monitoring is also required by 10 CFR 20.1502(a)(4) for any individual entering a high or very high radiation area.

The use of individual monitoring devices for external dose is required for the following:

- For adults who are likely to receive an annual dose in excess of any of the following:
  - 0.5 rem (0.005 Sv) DDE
  - 1.5 rems (0.015 Sv) eye dose equivalent
  - 5 rems (0.05 Sv) shallow-dose equivalent to the skin
  - 5 rems (0.05 Sv) shallow-dose equivalent to any extremity
- For minors who are likely to receive an annual dose in excess of any of the following:
  - 0.1 rem (1.0 mSv) DDE
  - 0.15 rem (1.5 mSv) eye dose equivalent
  - 0.5 rem (5 mSv) shallow-dose equivalent to the skin
  - 0.5 rem (5 mSv) shallow-dose equivalent to any extremity.
- For declared pregnant women who are likely to receive an annual dose from occupational exposure in excess of 0.1 rem (1.0 mSv) DDE, although the dose limit applies to the entire gestation period.
- For individuals entering a high or a very high radiation area.

If the licensee determines that monitoring the occupational exposure of some workers is not necessary, he/she must demonstrate to NRC that these workers will not exceed 10% of these limits using acceptable criteria. In these cases, the licensee need not provide individual monitoring devices to these workers.

The following are examples of criteria NRC accepts:

- The licensee has previous dosimeter monitoring reports for workers in a specific work area that show that the workers are not likely to receive a dose in excess of 10% of the limits;
- The licensee has performed appropriate radiation level surveys (using a survey meter or area thermoluminescent dosimeter (TLD)) of the work area, and has determined the number of hours a worker will be present in that work area, and has calculated the dose to workers (including "reasonable" accident scenarios) to show that the workers are not likely to receive a dose in excess of 10% of the limits;
- The licensee performs a reasonable calculation based upon source strength, distance, shielding, and time spent in the work area, that shows that workers are not likely to receive a dose in excess of 10% of the limits.

External dose is determined by using individual monitoring devices, such as film badges, optically stimulated luminescence dosimeters (OSL), or thermoluminescent dosimeters (TLDs). These devices must be evaluated by a processor that is National Voluntary Laboratory Accreditation Program (NVLAP)-approved, as required by 10 CFR 20.1501. Acceptable exchange frequencies are every 3 months for TLDs and OSLs and every month for film badges.

The device for monitoring the whole body dose, eye dose, skin dose, or extremity dose shall be placed near the location expected to receive the highest dose during the year (10 CFR 20.1201(c)). When the whole body is exposed fairly uniformly, the individual monitoring device is typically worn on the front of the upper torso.

If the radiation dose is highly non-uniform, causing a specific part of the whole body (head, trunk, arms above the elbow, or legs above the knees) to receive a substantially higher dose than the rest of the whole body, the individual monitoring device shall be placed near that part of the whole body expected to receive the highest dose. For example, if the dose rate to the head is expected to be higher than the dose rate to the trunk of the body, a monitoring device shall be located on or close to the head.

If, after the exposure is received, the licensee somehow learns that the maximum dose to a part of the whole body, eye, skin, or extremity was substantially higher than the dose measured by the individual monitoring device, an evaluation shall be conducted to estimate the actual maximum dose.

An acceptable alternative approach for highly non-uniform radiation fields is to use more than one dosimeter to separately track doses to different parts of the whole body. At the end of the year, each of the doses for each location is summed. The deep-dose equivalent recorded is that of the dosimeter location receiving the highest dose.

10 CFR 20.2106 requires that the recording for individual monitoring be done on NRC Form 5 or equivalent. NRC Form 5 is used to record doses received for the calendar year. The monitoring year may be adjusted as necessary to permit a smooth transition from one monitoring year to another, as long as the year begins and ends in the month of January, the change is made at the beginning of the year, and no day is omitted or duplicated in consecutive years.

Because evaluation of dose is an important part of the radiation protection program, it is important that users return dosimeters on time. Licensees shall be vigorous in their effort to recover any missing dosimeters. Delays in processing a dosimeter can result in the loss of the stored information.

If an individual's dosimeter is lost, the licensee needs to perform and document an evaluation of the dose the individual received and add it to the employee's dose record. Sometimes the most reliable method for estimating an individual's dose is to use his/her recent dose history. In other cases, particularly if the individual does non-routine types of work, it may be better to use doses of co-workers as the basis for the dose estimate.

Investigational Levels – External Dose Monitoring

NRC has emphasized that the investigational levels in this program are not new dose limits but, as noted in ICRP Report 26, "Recommendations of the International Commission on Radiological Protection," investigational levels serve as check points above which the results are considered sufficiently important to justify investigation.

When the cumulative annual exposure to a radiation worker exceeds Investigational Level I in Table L.1 (i.e., 10% of the annual limit for occupational exposure), the RSO should investigate the exposure and review the actions that might be taken to reduce the probability of recurrence. When the cumulative annual exposure exceeds Investigational Level II in Table L.1 (i.e., 30% of the annual limit for occupational exposure), the RSO will investigate the exposure and review actions to be taken to reduce the probability of recurrence, and management will review the report of the actions to be taken to reduce the probability of occurrence.

Table L.1 Investigational Levels.

Part of Body	Investigational Level I (mrems per year)	Investigational Level II (mrems per year)
whole body; head; trunk including male gonads; arms above the elbow; or legs above the knee	500 (5 mSv)	1500 (15 mSv)
hands; elbows; arms below the elbow; feet; knee; leg below the knee; or skin	5000 (50 mSv)	15,000 (150 mSv)
lens of the eye	1500 (15 mSv)	4500 (45 mSv)

The RSO will review and record on NRC Form 5, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring. The following actions will be taken at the investigational levels prescribed in Table L.1:

- Personnel dose less than Investigational Level I.

  Except when deemed appropriate by the RSO, no further action will be taken if an individual's dose is less than Table L.1 values for the Investigational Level I.

- Personnel dose equal to or greater than Investigational Level I but less than Investigational Level II.

  When the dose of an individual whose dose equals or exceeds Investigational Level I, the RSO will conduct a timely investigation and review the actions that might be taken to reduce the probability of recurrence, following the period when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the RSO. The RSO will, however, review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality and will make a record of the review.

- Personnel dose equal to or greater than Investigational Level II.

  The RSO should investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II. A consideration of actions should be taken by the RSO to reduce the probability of occurrence, and a report of the actions should be reviewed by the licensee's management at its first meeting following completion of the investigation.

- Re-establishment of Investigational Level II to a level above that listed in Table L.1.

In cases where a worker's or a group of workers' doses need to exceed an Investigational Level, a new, higher Investigational Level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new Investigational Levels should be documented.

Declared Pregnancy and Dose to Embryo/Fetus

10 CFR 20.1208 states that the licensee shall ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). The licensee shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman. The pregnancy is declared in writing, and includes the worker's estimated date of conception. The dose to an embryo/fetus shall be taken as the sum of:

- The deep-dose equivalent to the declared pregnant woman; and
- The dose to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

Methods for calculating the radiation dose to the embryo/fetus can be found in Regulatory Guide 8.36, "Radiation Dose To the Embryo/Fetus."

Internal Dose Exposure

With respect to internal exposure, you are required to monitor occupational intake of radioactive material and assess the resulting dose if it appears likely that personnel will receive greater than 10% of the annual limit on intake (ALI) from intakes in 1 year. 10 CFR Part 20 provides terms for radionuclide intakes by means of inhalation and ingestion, i.e., derived air concentration (DAC) and ALI.

The DAC for each class of radionuclide is the concentration of airborne radioactivity in μCi/ml that, if an occupational worker were to be continuously exposed to for 2,000 hours (1 year), would result in either a CEDE of 5 rems (0.05 Sv) to the whole body or a committed dose equivalent of 50 rems (0.5 Sv) to any individual organ or tissue, with no consideration for the contribution of external dose. The ALI and DAC for each radionuclide in a specific chemical form are listed in 10 CFR Part 20, Appendix B.

For each class of each radionuclide, there are two ALIs, one for ingestion and one for inhalation. The ALI is the quantity of radioactive material that, if taken into the body of an adult worker by the corresponding route, would result in a committed effective dose equivalent of 5 rems (0.05 Sv) or a committed dose equivalent of 50 rems (0.5 Sv) to any individual organ or tissue, again, with no consideration for the contribution of external dose.

The total effective dose equivalent concept makes it possible to combine both the internal and external doses in assessing the overall risk to the health of an individual. The 10 CFR Part 20 ALI and DAC numbers reflect the doses to all principal organs that are irradiated. The ALI and DAC were derived by multiplying a unit intake by the appropriate organ weighting factors (W_T), for the organs specifically targeted by the radionuclide compound, and then summing the organ-weighted doses to obtain a whole body risk-weighted "effective dose." Per 10 CFR Part 20, Appendix B, when an ALI is defined by the stochastic dose limit, this value alone is given. When the ALI is determined by the non-stochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parentheses.

The types and quantities of radioactive material manipulated at most medical facilities do not provide a reasonable possibility for an internal intake by workers. However, uses such as preparing radioiodine capsules from liquid solutions, and opening and dispensing radioiodine from vials containing millicurie quantities require particular caution. To monitor internal exposures from such operations, a routine bioassay program to periodically monitor workers should be established.

A program for performing thyroid uptake bioassay measurements should include adequate equipment to perform bioassay measurements, procedures for calibrating the equipment, including factors necessary to convert counts per minute into becquerel or microcurie units, and should address the technical problems commonly associated with performing thyroid bioassays (e.g., statistical accuracy, attenuation by neck tissue). Thyroid bioassay procedures should also specify the interval between bioassays, action levels, and the actions to be taken at those levels. For guidance on developing bioassay programs and determination of internal occupational dose and summation of occupational dose, refer to Regulatory Guide 8.9, Revision 1, Acceptable Concepts, Models, Equations and Assumptions for a Bioassay Program" dated July 1993, Regulatory Guide 8.34, "Monitoring Criteria and Methods to Calculate Occupational Radiation Doses," dated July 1992, and NUREG-1400, "Air Sampling in the Workplace," dated September 1993.

Recordkeeping

Records of measurement data, calculations of intakes, and methods for calculating dose must be maintained as required by 10 CFR 20.1204(c), 20.2103, and 20.2106. For additional information on recordkeeping and reporting occupational exposure data, including intakes, refer to Revision 1 of Regulatory Guide 8.7, "Instructions for Recording and Reporting Occupational Radiation Exposure Data."

Summation of External and Internal Doses

Pursuant to 10 CFR 20.1202, the external and internal doses must be summed if required to monitor both under 10 CFR 20.1502.

Appendix M

Guidance for Demonstrating That Individual Members of the Public Will Not Receive Doses Exceeding the Allowable Limits

Guidance for Demonstrating that Individual Members of the Public Will Not Receive Doses Exceeding the Allowable Limits

Licensees must ensure that:

- The radiation dose received by individual members of the public does not exceed 1 mSv (100 mrem) in one calendar year resulting from the licensee's possession and/or use of licensed materials. [10 CFR 20.1301(a)(1)]

> Members of the public include persons who live, work, or may be near locations where licensed material is used or stored and employees whose assigned duties do not include the use of licensed materials and who work in the vicinity where it is used or stored.

- The radiation dose in unrestricted areas does not exceed 0.02 mSv (2 mrem) in any one hour. [10 CFR 20.1301(a)(2)]

> Typical unrestricted areas may include offices, shops, laboratories, areas outside buildings, property, and nonradioactive equipment storage areas. The licensee does not control access to these areas for purposes of controlling exposure to radiation or radioactive materials; however, the licensee may control access to these areas for other reasons, such as security.

Licensees must show compliance with both portions of the regulation. For areas adjacent to facilities where licensed material is used or stored, calculations or a combination of calculations and measurements (e.g., using an environmental TLD) are often used to show compliance.

Calculation Method[1]

The calculational method takes a tiered approach, going through a four-part process, starting with a worst case situation and moving toward more realistic situations. It makes the following simplifications:

- Licensed material is a point source;
- Typical radiation levels encountered when the source is in the shielded position are taken from the manufacturer's literature; and

[1] For ease of use, the examples in this appendix use conventional units. The conversions to SI units are as follows: 1 foot (ft) = 0.305 meter; 1 mrem = 0.01 mSv.

- Credit is taken for any shielding found between the licensed material and the unrestricted areas.

Part 1 of the calculational method is simple but conservative. It assumes that an affected member of the public is present 24 hours a day and uses only the inverse square law to determine if the distance between the licensed material and the affected member of the public is sufficient to show compliance with the public dose limits. Part 2 considers not only distance, but also the time that the affected member of the public is actually in the area under consideration. Part 3 considers the distance, the portion of time and dose rate during source exposure, the portion of time and dose rate while the source is in the shielded position, and the portion of time that the affected member of the public is present. Part 4 considers the approach in Part 3 plus any additional shielding between the licensed material and the unrestricted area. Using this approach, licensees make only those calculations that are needed to demonstrate compliance. The results of these calculations typically result in higher radiation levels than would exist at typical facilities, but provide a method for estimating conservative doses that could be received.

Example 1

To better understand the calculation method, we will examine Therapy Clinic, an HDR Afterloading Device licensee. Yesterday, the clinic's president noted that the new HDR facility is close to his secretary's desk and he asked Joe, the RSO, to determine if the clinic is complying with NRC's regulations.

The secretary's desk is near the wall separating the reception area from the designated, locked HDR room where the clinic has located its unit. Joe measures the distance from the HDR unit to the wall and assumes that the device would have the maximum dose rate when the source is exposed: 5000 mrem per hour at one meter. This is the maximum dose rate during treatment time. Figure M.1 is Joe's sketch of the areas in question, and Table M.1 summarizes the information Joe has on the HDR unit.

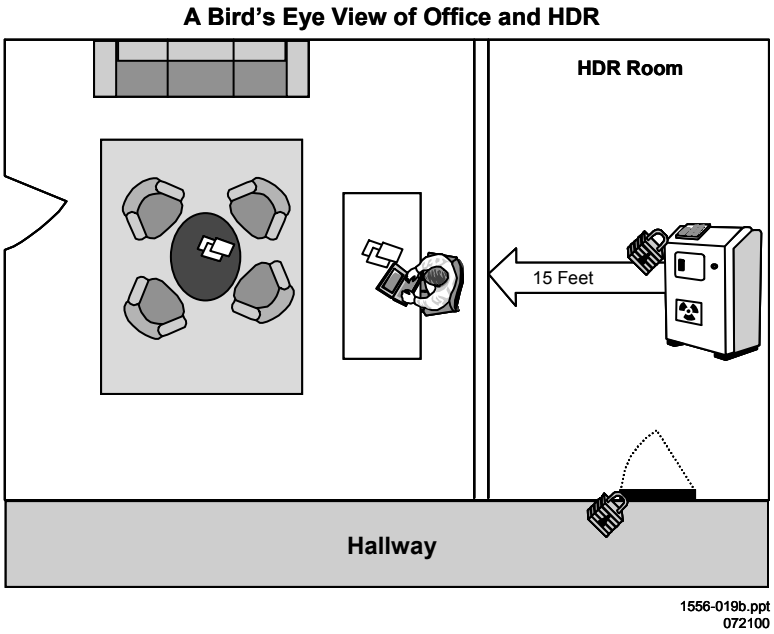

Figure M.1 Diagram of Office and HDR Facility. *This sketch shows the areas described in Examples 1 and 2.*

Table M.1 Information Known About the HDR Unit.

Description of Known Information	**Ir-192/HDR/10 Ci**
Dose rate in mrem/hour encountered at specified distance from the HDR unit (from manufacturer)	5000 mrem/hour at 1 meter (3.28 ft)
Distance in ft to secretary's chair	15 ft

Example 1: Part 1

Joe's first thought is that the distance between the HDR unit and the secretary's chair may be sufficient to show compliance with the regulation in 10 CFR 20.1301. So, taking a worst case approach, he assumes that the HDR unit is constantly present with a patient undergoing treatment and the secretary is constantly sitting in the desk chair (i.e., 24 hours a day). Joe proceeds to calculate the dose she might receive hourly and yearly from the HDR unit as shown in Table M.2 below.

Table M.2 Calculational Method, Part 1: Hourly and Annual Dose Received From the HDR Unit.

Step No.	Description	Input Data	Results
1	Dose received in an hour at known distance from the HDR unit (e.g., from the manufacturer), in mrem/hour	5000	5000
2	Square of the distance (ft) at which the Step 1 rate was measured, in ft^2	$(3.28)^2$	10.8
3	Square of the distance (ft) from the HDR unit to the secretary's desk in an unrestricted area, in ft^2	$(15.0)^2$	225
4	Multiply the results of Step 1 by the results of Step 2 (this is an intermediate result)	5000 x 10.8	54000
5	Divide the result of Step 4 by the result of Step 3 to calculate the dose received by an individual at the secretary's desk**, HOURLY DOSE RECEIVED FROM THE HDR UNIT**, in mrem in an hour	54000/225	**240**
6	Multiply the result of Step 5 by 24 hours/day x 366 (leap year) days/year = **MAXIMUM ANNUAL DOSE RECEIVED FROM THE HDR UNIT**, in mrem in a year	240 x 24 x 366	**2108000**

Note: The result in Step 5 does not demonstrate compliance with the 2 mrem in any one hour limit. Also, if the result in Step 6 exceeds 100 mrem/year, proceed to Part 2 of the calculation method.

At this point, Joe notes that the total dose that an individual could receive in any one hour greatly exceeds 2 mrem in an hour (i.e., 240 mrem in an hour) and notes that an individual could receive a dose of 2,108,000 mrem in a year, much higher than the 100 mrem limit.

Example 1: Part 2

Joe reviews his assumptions and recognizes that the secretary is not at the desk 24 hours/day. He decides to make a realistic estimate of the number of hours the secretary sits in the chair at the desk, keeping his other assumptions (the HDR unit is constantly present and in use) constant (24 hours/day). He then recalculates the annual dose received.

Table M.3 Calculational Method, Part 2: Annual Dose Received From the HDR Unit.

Step No.	Description	Results
7	A. Average number of hours per day that individual spends in area of concern (e.g., secretary sits at desk 5 hours/day; the remainder of the day the secretary is away from the desk area copying, filing, etc.) B. Average number of days per week in area (e.g., secretary is part time and works 3 days/week) C. Average number of weeks per year in area (e.g., secretary works all year)	5.0 3.0 52
8	Multiply the results of Step 7.A. by the results of Step 7.B. by the results of Step 7.C. = **AVERAGE NUMBER OF HOURS IN AREA OF CONCERN PER YEAR**	5.0 x 3.0 x 52 = **780**
9	Multiply the results in Step 5 by the results of Step 8 = **ANNUAL DOSE RECEIVED FROM THE HDR UNIT CONSIDERING REALISTIC ESTIMATE OF TIME SPENT IN AREA OF CONCERN**, in mrem in a year	240 x 780 = **187000**

Note: If Step 9 exceeds 100 mrem in a year, proceed to Part 3 of the calculation method.

Although Joe is pleased to note that the calculated annual dose received is significantly lower, he realizes it still greatly exceeds the 100 mrem in a year limit.

Example 1: Part 3

Again Joe reviews his assumptions and recognizes that the HDR unit is not constantly in use when the secretary is seated at the desk. As he examines the situation, he realizes he must take these factors into account.

Table M.4 Calculational Method, Part 3: Summary of Information.

Step No.	Description	Input
10	Dose rate while the source is in the shielded position, in mrem per hour at 3.28 ft from the HDR (from manufacturer)	0.02
11	Dose rate while patient is being treated, in mrem per hour at 3.28 ft from the HDR	5000
12	Maximum number of patients treated per hour	2
13	Maximum treatment time, in minutes	1
14	From Table M.1, distance from HDR to secretary, in feet	15
15	From Step 8, average number of hours that secretary is in area of concern, per year	780

Table M.5 Calculational Method, Part 3: Annual Dose Received from HDR.

Step No.	Description	Result
16	[60 minus the input from Step 12 multiplied by (the input from Step 13)] divided by 60 = [60 - 2 x (1)] / 60 = [60 - 2] / 60 = **FRACTION OF TIME THE SOURCE IS IN THE SHIELDED POSITION**	**0.97**
17	1.0 minus the result from Step 16 = 1 - 0.97 = **FRACTION OF TIME THE HDR UNIT IS USED**	**0.03**
18	(The input from Step 10 multiplied by the result from Step 16) plus (the input from Step 11 multiplied by the result from Step 17) = (0.02 x 0.97) + (5000 x 0.03) = 0.02 + 150 = **AVERAGE DOSE ENCOUNTERED AT 3.28 FEET FROM THE HDR UNIT, in mrem in an hour.**	**150**
19	The result from Step 18 multiplied by (3.28 squared divided by the input from Step 14 squared) = 150 x (3.28^2 / 15^2) = 150 x (10.8 / 225) = **AVERAGE DOSE RATE ENCOUNTERED BY THE SECRETARY, in mrem per hour.**	**7.20**
20	The result from Step 19 multiplied by the input from Step 15 = 780 x 7.20 = **ANNUAL DOSE RECEIVED FROM HDR UNIT CONSIDERING REALISTIC ESTIMATES OF TIME SPENT IN AREA OF CONCERN, DOSE RATES, AND HDR UNIT USAGE, in mrem in a year.**	**5600**

Note: If the result in Step 20 is greater than 100 mrem/yr, the licensee must take corrective actions. Corrective action may include shielding the HDR treatment room.

Although Joe notes that the result in Step 20 is significantly lower, he realizes that the result still exceeds the 100 mrem in a year limit and that he must consider additional corrective actions. As he reviews the situation, he realizes that the walls of the treatment room consist of approximately 10.5 inches of concrete. He decides to take this into account.

Example 1: Part 4

Table M.6 Calculational Method, Part 4: Summary of Information.

Step No.	Description	Input
21	Tenth Value Layer for Iridium 192 in concrete in inches	4.2
22	Thickness of concrete in wall	10.5
23	Annual dose received from HDR unit from Step No. 20, in mrem in a year.	5600

Table M.7 Calculational Method, Part 4: Annual Dose Received from HDR.

Step No.	Description	Result
24	[Input from Step 22 divided by the input from Step 21] = [10.5/4.2] = **NUMBER OF TENTH VALUE LAYERS**	**2.5**
25	[Input from Step 23 divided by 10 raised to the result from Step 24] = $5600/10^{2.5}$ = **ANNUAL DOSE RECEIVED FROM HDR UNIT CONSIDERING REALISTIC ESTIMATES OF TIME SPENT IN AREA OF CONCERN, DOSE RATES, HDR UNIT USAGE, AND TREATMENT ROOM SHIELDING, in mrem in a year**	**18**

Joe is glad to see that the results in Step 25 show compliance with the 100 mrem in a year limit. Had the result in Step 25 been higher than 100 mrem in a year, then Joe could have done one or more of the following:

- Consider whether the assumptions used to determine occupancy are accurate, revise the assumptions as needed, and recalculate using the new assumptions;
- Calculate the effect of any additional shielding[2] located between the HDR unit and the secretarial workstation;
- Take corrective action (e.g., move the secretarial workstation) and perform new calculations to demonstrate compliance;
- Designate the area outside the use area as a restricted area and the secretary as an occupationally exposed individual. This would require controlling access to the area for purposes of radiation protection and training the secretary as required by 10 CFR 19.12.

Note that in the example, Joe evaluated the unrestricted area outside only one wall of the HDR facility. Licensees also need to make similar evaluations for other unrestricted areas and to keep in mind the ALARA principle, taking reasonable steps to keep radiation doses received below regulatory requirements. In addition, licensees need to be alert to changes in situations (e.g., changing the secretary to a full-time worker, or changing the estimate of the portion of time spent at the desk) and to perform additional evaluations, as needed.

RECORDKEEPING: 10 CFR 20.2107 requires licensees to maintain records demonstrating compliance with the dose limits for individual members of the public.

Combination Measurement – Calculational Method

This method, which allows the licensee to take credit for shielding between the HDR unit and the area in question, begins by measuring radiation levels in the areas, as opposed to using manufacturer-supplied rates at a specified distance from the unit. These measurements must be made with calibrated survey meters sufficiently sensitive to measure background levels of radiation; however, licensees must exercise caution when making these measurements, and they must use currently calibrated radiation survey instruments. A maximum dose of 1 mSv (100 mrem) received by an individual over a period of 2080 hours (i.e., a "work year" of 40 hours/week for 52 weeks/year) is less than 0.5 microsievert (0.05 mrem) per hour.

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[2] NCRP Report No. 49, " Structural Shielding Design and Evaluation for Medical Use of X Rays and Gamma Rays of Energies Up to 10 MeV," contains helpful information. It is available from the National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Suite 800, Bethesda, Maryland 20814. NCRP's telephone numbers are: (301) 657-2652 or 1-800-229-2652.

This rate is well below the minimum sensitivity of most commonly available G-M survey instruments.

Instruments used to make measurements for calculations must be sufficiently sensitive. An instrument equipped with a scintillation-type detector (e.g., NaI(Tl)) or a micro-R meter used in making very low gamma radiation measurements should be adequate.

Licensees may also choose to use environmental TLDs[3] in unrestricted areas next to the HDR unit for monitoring. This direct measurement method would provide a definitive measurement of actual radiation levels in unrestricted areas without any restrictive assumptions. Records of these measurements can then be evaluated to ensure that rates in unrestricted areas do not exceed the 1 mSv/year (100 mrem/year) limit.

Example 2

As in Example 1, Joe is the RSO for Therapy Clinic, an HDR licensee. The clinic has one HDR unit in a designated, locked area that adjoins an unrestricted area where a secretarial work station is located. Figure M-1 and Table M-2 have more information. Joe wants to see if the clinic complies with the public dose limits at the secretarial station.

Joe placed an environmental TLD badge in the secretarial work space for 30 days. The TLD processor sent Joe a report indicating the TLD received 1 mSv (100 mrem).

[3] TLDs used for personnel monitoring (e.g., LiF) may not have sufficient sensitivity for this purpose. Generally, the minimum reportable dose received is 0.1 mSv (10 mrem). Suppose a TLD monitors dose received and is changed once a month. If the measurements are at the minimum reportable level, the annual dose received could have been about 1.2 mSv (120 mrem), a value in excess of the 1 mSv/year (100 mrem/year) limit. If licensees use TLDs to evaluate compliance with the public dose limits, they should consult with their TLD supplier and choose more sensitive TLDs, such as those containing CaF2 that are used for environmental monitoring.

Example 2: Part 1

Table M.8 Combination Measurement – Calculational Method.

Step No.	Description	Input Data and Results
1	**Dose** received by TLD, in mrem	**100**
2	**Total hours** TLD exposed	24 hours/day x 30 days/month = **720**
3	Divide the results of Step 1 by the results of Step 2 = **HOURLY DOSE RECEIVED**, in mrem in an hour	100/720 = **0.14**
4	Multiply the results of Step 3 by 366 days/year [leap year] x 24 hours/day = 8760 hours in one year = **MAXIMUM ANNUAL DOSE RECEIVED FROM THE HDR UNIT**, in mrem in a year	366 x 24 x 0.14 = 8784 x 0.14 = **1230**

Note: For the conditions described above, Step 3 indicates that the dose received in any one hour is less than the 2 mrem in any one hour limit. However, if there are any changes, then the licensee will need to reevaluate the potential doses that could be received in any one hour. Step 4 indicates that the annual dose received would be much greater than the 100 mrem in a year allowed by the regulations.

Example 2: Part 2

At this point Joe can adjust for a realistic estimate of the time the secretary spends in the area and the time the HDR unit was operating, as he did in Parts 2 and 3 of Example 1.

Example 2: Part 3

If the results of Joe's evaluation in Part 2 show that the annual dose received in a year exceeds 100 mrem, then he may have to consider moving the secretary's desk or adding additional shielding to the wall.

Appendix N

Emergency Procedures

Emergency Procedures

Model Spill Procedures – Low and High Dose Unsealed Sources

This model provides acceptable procedures for responding to emergencies. You may either adopt this model procedure or develop your own procedures to meet the requirements of 10 CFR 20.1101.

Minor Spills of Liquids and Solids

1. Notify persons in the area that a spill has occurred.
2. Prevent the spread of contamination by covering the spill with absorbent paper.
3. Wearing gloves and protective clothing such as a lab coat and booties, clean up the spill using absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a "caution radioactive material" labeled bag for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.
4. Survey the area with a low-range radiation detection survey instrument sufficiently sensitive to detect the radionuclide. Smear the area to ensure contamination is below trigger levels. Check the area around the spill. Also check hands, clothing, and shoes for contamination.
5. Report the incident to the RSO.

Major Spills of Liquids and Solids

1. Clear the area. Notify all persons not involved in the spill to vacate the room.
2. Prevent the spread of contamination by covering the spill with "caution radioactive material" labeled absorbent paper, but do not attempt to clean it up. To prevent the spread of contamination, clearly indicate the boundaries of the spill and limit the movement of all personnel who may be contaminated.
3. Shield the source if possible. Do this only if it can be done without further contamination or a significant increase in radiation exposure.
4. Close the room and lock or otherwise secure the area to prevent entry.
5. Notify the RSO immediately.
6. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water, then washing with mild soap. If contamination remains, the RSO may consider inducing perspiration. Then wash the affected area again to remove any contamination that was released by the perspiration.

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident-specific variables, such as the number of individuals affected, other hazards present, likelihood of contamination spread, types of surfaces contaminated and radiotoxicity of the spilled material. For some spills of radionuclides with half-lives shorter than 24 hours and in amounts less than five times the lowest ALI, an alternative spill procedure may be restricted access pending complete decay.

***Note**: A report to NRC may be required pursuant to 10 CFR 30.50.*

Use Table N-1 as general guidance to determine whether a major spill procedure or a minor spill procedure will be implemented.

Estimate the amount of radioactivity spilled. Initiate a major or minor spill procedure, based on the following information. Spills above these mCi amounts are considered major, and below these levels are considered minor.

Table N.1 Relative Hazards of Common Radionuclides.

Radionuclide	Millicuries	Radionuclide	Millicuries
P-32	1	Tc-99m	100
Cr-51	100	In-111	10
Co-57	10	I-123	10
Co-58	10	I-125	1
Fe-59	1	I-131	1
Co-60	1	Sm-153	10
Ga-67	10	Yb-169	10
Se-75	1	Hg-197	10
Sr-85	10	Au-198	10
Sr-89	1	Tl-201	100

Spill Kit

Assemble a spill kit that contains the following items:

- Disposable gloves and housekeeping gloves;
- Disposable lab coats;

- Disposable head coverings;
- Disposable shoe covers;
- Roll of absorbent paper with plastic backing;
- Masking tape;
- Plastic trash bags with twist ties;
- "Radioactive Material" labeling tape;
- Marking pen;
- Pre-strung "Radioactive Material" labeling tags;
- Contamination wipes;
- Instructions for "Emergency Procedures";
- Clipboard with copy of Radioactive Spill Report Form;
- Pencil;
- Appropriate survey instruments, including batteries.

Emergency Surgery of Patients Who Have Received Therapeutic Amounts of Radionuclides

If AUs or other personnel involved in the surgical procedure are likely to receive exposures exceeding the non-occupational permissible dose limits specified in 10 CFR 20.1301, we will follow the procedures below:

1. If emergency surgery is performed within the first 24 hours following the administration of I-131 sodium iodide, fluids (e.g., blood, urine) will be carefully removed and contained in a closed system.
2. Protective eye wear will be worn by the surgeon and any personnel involved in the surgical procedure for protection of the eyes from possible splashing of radioactive material and exposure from beta radiation (if applicable).
3. The RSO will direct personnel in methods to keep doses ALARA during surgical procedures.
4. If an injury occurs during surgery that results in a cut or tear in the glove used, the individual involved will be monitored to determine if radioactive material was introduced into the wound. The RSO will be informed of any possible radiation hazard.

Autopsy of Patients Who Have Received Therapeutic Amounts of Radionuclides

If AUs or other personnel involved in the autopsy are likely to receive exposures exceeding the non-occupational permissible dose limits specified in 10 CFR 20.1301, we will follow the procedures below:

1. Upon the death of the therapy patient, the AU in charge and the RSO will be notified immediately.
2. An autopsy will be performed only after consultation and permission from the RSO.
3. Protective eye wear will be worn by the pathologist and his assistants for protection from possible splashing of radioactive material and exposure from beta radiation.
4. If an entire section of tissue containing the radionuclide can be removed during autopsy, this will be done first. The remainder of the autopsy can then proceed as usual.
5. The RSO will evaluate the radiation hazard(s), direct personnel in safety and protection, and suggest suitable procedures in order to keep doses ALARA during the autopsy.
6. When possible, separate organs will be promptly removed from the body, and detailed dissection will be carried out a safe distance away from the body.
7. After selected small samples have been removed, the radioactive tissues that are retained will promptly be either placed in appropriately shielded vessels for storage or disposed of according to procedures deemed appropriate by the RSO and in accordance with the regulations.
8. If an injury occurs during the autopsy that results in a cut or tear in the glove, the individual will be monitored to determine if radioactive material was introduced into the wound. The RSO will be informed on any possible radiation hazard.

Model Emergency Procedures for Teletherapy Units Containing Sealed Sources – Emergency Procedures for Beam Control Failure or Malfunction

This model provides acceptable procedures for responding to emergencies. You may either adopt this model procedure or develop your own procedures to meet the requirements of 10 CFR 20.1101 and 10 CFR 35.610.

If the light signals or beam-on monitor indicates that the beam control mechanism has failed to terminate the exposure at the end of the pre-set time (e.g., if the red light stays on and the green light is off, or if both the red and the green lights stay on for more than a few seconds), the source may still be in the exposed position. The following steps are to be carried out promptly:

- Open the door to the treatment room.
- Tell an ambulatory patient to leave the room.

- If the patient is not ambulatory, enter the treatment room but avoid exposure to the direct beam. Pull the treatment table as far away from the direct beam as possible. Transfer the patient to a stretcher and remove the patient from the room.
- Close the door and secure the area by locking the door to the treatment room or posting a guard at the entrance.
- Turn off the main switch at the control panel.
- Notify the AU and RSO at once.
- Conspicuously post a sign in the area to warn others of the problem.

Authorized User: _____

Phone No.: On Duty: _____ Off Duty: _____

Radiation Safety Officer: _____

Phone No.: On Duty: _____ Off Duty: _____

Appendix O

Model Procedures for Ordering and Receiving Packages

Model Procedures for Ordering and Receiving Packages

This model provides acceptable procedures for ordering and receiving packages containing licensed material.

Model Guidance

- We will, through a designee (e.g., RSO), authorize each order of radioactive materials and ensure that the requested materials and quantities are authorized by the license for use by the requesting AU and that possession limits are not exceeded.
- We will establish and maintain a system for ordering and receiving radioactive material. The system will contain the following information:
  - — Records that identify the AU or department, radionuclide, physical and/or chemical form, activity, and supplier;
  - — Confirmation, through the above records, that material received was ordered through proper channels.
- For deliveries during normal working hours, we will inform carriers to deliver radioactive packages directly to a specified area.
- For deliveries during off-duty hours, we will inform security personnel or other designated persons to accept delivery of radioactive packages in accordance with procedures outlined in the sample memorandum for delivery of packages to the Nuclear Medicine Division, provided below. We will develop a similar memorandum for delivery of packages to other divisions.

Sample Memorandum

MEMO TO: Chief of Security
FROM: Radiation Safety Officer
SUBJECT: Receipt of Packages Containing Radioactive Material

The security guard on duty will accept delivery of radioactive material that arrives outside normal working hours. Packages will be taken immediately to the Nuclear Medicine Division, Room __ . Unlock the door, place the package on top of the counter, and relax the door.

If the package appears to be damaged, immediately contact one of the individuals identified below. Ask the carrier to remain at the hospital until it can be determined that neither the driver nor the delivery vehicle is contaminated.

If you have any questions concerning this memorandum, please call our hospital Radiation Safety Officer, at extension _____.

	Name	**Home Telephone**
Radiation Safety Officer:		
Director of Nuclear Medicine:		
Nuclear Medicine Technologist Supervisor:		
Nuclear Medicine Technologist on call (call page operator at extension _____)		
Nuclear Medicine Physician on call (call page operator at extension _____)		

Appendix P

Model Procedure for Safely Opening Packages Containing Radioactive Material

Model Procedure for Safely Opening Packages Containing Radioactive Material

This model provides acceptable procedures for opening packages containing radioactive material. You may either adopt this model procedure or develop your own procedure to meet the requirements of 10 CFR 20.1906.

Special requirements must be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits specified in 49 CFR 173.433 or in Table A-1 of 10 CFR Part 71 (e.g., 13.5 curies of Mo-99, Cs-137, Ir-192; 54.1 curie of I-125; 541 curies of Xe-133, or 216 curies of Tc-99m). Such packages must be received expeditiously when the carrier offers it for delivery or when the carrier notifies the licensee that the package has arrived at the carrier's terminal. For these and other packages that are so required, monitoring for external radiation levels and surface contamination must be performed within 3 hours of receipt (if received during working hours) or no later than 3 hours from the beginning of the next working day (if received after working hours), in accordance with the requirements of 10 CFR 20.1906(c). The NRC Regional Office and the final delivery carrier must be notified if the following conditions apply:

- Removable radioactive surface contamination exceeds the limits of 10 CFR 71.87(i) [i.e. 22 dpm/centimeter squared (cm^2) of beta and gamma emitting photons and 2.2 dpm/cm^2 of alpha]; and
- External radiation levels exceed the limits of 10 CFR 71.47.

We will implement the following procedure for opening each package containing radioactive material received under our NRC license:

1. Put on gloves to prevent hand contamination.
2. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO immediately.
3. Monitor the external surfaces of a labeled[1] package for radioactive contamination, unless the package contains only radioactive material in the form of a gas or in special form, as defined in 10 CFR 71.4.
4. Monitor the external surfaces of a labeled[1] package for radiation levels, unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in 10 CFR 71.4 and Table A to 10 CFR Part 71.

[1] Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in DOT regulations, 49 CFR 172.403 and 172.436-440.

5. Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels, if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.
6. Remove the packing slip.
7. Open the outer package, following any instructions that may be provided by the supplier.
8. Open the inner package and verify that the contents agree with the packing slip.
9. Check the integrity of the final source container. Notify the RSO of any broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
10. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. An appropriate instrument with sufficient sensitivity will be used to assay the sample. For example, a NaI(T1) crystal and ratemeter, a liquid scintillation counter, or a proportional flow counter may be used for these assays. The detection efficiency will be determined to convert wipe sample counts per minute to disintegrations per minute. ***Note:*** *a dose calibrator is not sufficiently sensitive for this measurement.* Take precautions against the potential spread of contamination.
11. Check the user request to ensure that the material received is the material that was ordered.
12. Monitor the packing material and the empty packages for contamination with a radiation detection survey meter before discarding. If contaminated, treat this material as radioactive waste. If not contaminated, remove or obliterate the radiation labels before discarding in in-house trash.
13. Make a record of the receipt.

For packages received under the general license in 10 CFR 31.11, we will implement the following procedure for opening each package:

1. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO immediately.

2. Check to ensure that the material received is the material that was ordered.

Appendix Q

Model Leak Test Program

Model Leak Test Program

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, leak tests should be analyzed in a low-background area.
- Consider using a NaI(Tl) well counter system with a single or multichannel analyzer to analyze samples obtained from gamma-emitting sources (e.g., Cs-137).
- Consider using a liquid scintillation or gas-flow proportional counting system to analyze samples obtained from beta-emitting sources (e.g., Sr-90).
- Instrumentation used to analyze leak test samples must be capable of detecting 0.005 microcurie of radioactivity.

Model Procedure for Performing Leak Testing and Analysis

This model provides acceptable procedures for sealed source leak testing and analysis.

- For each source to be tested, list identifying information such as sealed source serial number, radionuclide, and activity.
- Use a separate wipe sample (e.g., cotton swab or filter paper) for each source.
- Number each wipe to correlate identifying information for each source.
- Wear gloves.
- Obtain samples at the most accessible area where contamination would accumulate if the sealed source were leaking.
- Measure the background count rate and record.
- Check the instrument's counting efficiency, using either a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards should be within ± 5% of the stated value and traceable to a primary radiation standard, such as those maintained by NIST.
- Calculate efficiency of the instrument.

  For example: $\frac{[(\text{cpm from std}) - (\text{cpm from bkg})]}{\text{activity of std in microcuries}}$ = efficiency in cpm/microcurie

  where: cpm = counts per minute
  std = standard
  bkg = background

- Analyze each wipe sample to determine net count rate.
- For each sample, calculate the activity in microcuries and record.

  For example: $\frac{\text{[(cpm from wipe sample) - (cpm from bkg)]}}{\text{efficiency in cpm/microcurie}}$ = microcuries on wipe sample

- Leak test records will be retained in accordance with 10 CFR 35.2067 for 3 years. The records must contain:
  - The model number and serial number (if assigned) of each source tested;
  - The identity of each source radionuclide and its estimated activity;
  - The measured activity of each test sample expressed in microcuries;
  - A description of the method used to measure each test sample;
  - The date of the test; and
  - The name of the individual who performed the test.
- If the wipe test activity is 0.005 microcurie (185 Bq) or greater:
  - Immediately withdraw the sealed source from use and either store the source, dispose of the source, or cause the source to be repaired, in accordance with the requirements in 10 CFR Parts 20 and 30.
  - File a report within 5 days of the leakage test with the appropriate NRC Regional Office listed in 10 CFR 30.6.

Appendix R

Model Procedure for Area Surveys

Model Procedure for Area Surveys

This model provides acceptable procedures for surveys. You may either adopt these model procedures or develop your own procedures to meet the requirements of 10 CFR 20.1101, 10 CFR 20.1501, and 10 CFR 35.70.

Ambient Radiation Level Surveys

We will implement the following procedure for ambient radiation level surveys:

- Dose-rate surveys, at a minimum, will be performed in locations where:
  - — Workers are exposed to radiation levels that might result in radiation doses in excess of 10% of the occupational dose limits; or
  - — An individual is working in an environment with a dose rate of 2.5 mrem/hour or more (5 rem/year divided by 2,000 hour/year).
- 10 CFR 20.1301 requires that the TEDE to an individual member of the public from the licensed operation does not exceed 1 mSv (0.1 rem) in a year, and that the dose in any unrestricted area from external sources does not exceed 0.02 mSv (0.002 rem) in any one hour. Appropriate surveys will be conducted to assure that the requirements of 10 CFR 20.1301 are met.
- Radiation level surveys will consist of measurements with a survey meter sufficiently sensitive to detect 0.1 milliroentgen (mR) per hour. The following areas and frequencies will be followed:
  - — Survey at the end of each day of use all radiopharmaceutical elution, preparation, assay and administration areas (except patient rooms, which will be surveyed at the end of the therapy instead of on the day of administration) when using radiopharmaceuticals requiring a written directive (e.g., all therapy dosages and any iodine-131 dosage exceeding 30 μCi).
  - — Survey monthly all laboratory areas where only small quantities of gamma-emitting radioactive material are used (< 200 μCi at a time).
  - — Survey weekly all radionuclide use, storage, and waste storage areas. If diagnostic administrations are occasionally made in patients' rooms (e.g., bone scan injections, Tc-99m heart agents) and special care is taken to remove all paraphernalia, those rooms need not be surveyed.
  - — Survey quarterly all sealed source and brachytherapy source storage areas.
- The RSO will be notified immediately of radiation levels that exceed trigger levels. Trigger levels for restricted and unrestricted areas are presented in Table R-1.

Table R.1 Ambient Dose Rate Trigger Levels.

Type of Survey	Area Surveyed	Trigger Level
Ambient Dose Rate	Unrestricted	0.1 mR/hr
Ambient Dose Rate	Restricted	5.0 mR/hr

Contamination Surveys

Facilities and Equipment:

- To ensure achieving the required sensitivity of measurements, survey samples will be analyzed in a low-background area.
- The table titled "Stationary Instruments Used to Measure Wipe, Bioassay, and Effluent Samples" in Appendix I provides examples of appropriate instruments.

Contamination surveys will be sufficient to identify areas of contamination that might result in doses to workers or to the public. Combined removable and fixed contamination will be surveyed using appropriate radiation detection equipment. Removable contamination can be detected and measured by conducting a wipe test of the surface, counted in an appropriate counting instrument, such as a liquid scintillation counter, a sodium iodide or germanium gamma counter, or a proportional alpha/beta counter.

We will implement the following procedure for contamination surveys:

- Contamination surveys are performed:
  - — To evaluate radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment;
  - — After any spill or contamination event;
  - — When procedures or processes have changed;
  - — To evaluate contamination of users and the immediate work area, at the end of the day, when licensed material is used;
  - — In unrestricted areas at frequencies consistent with the types and quantities of materials in use, but not less frequently than monthly;
  - — In areas adjacent to restricted areas and in all areas through which licensed materials are transferred and temporarily stored before shipment.
- Personnel will survey for contamination in locations where individuals are working with an unsealed form of radioactive material.

- The method for performing removable contamination surveys must be sufficiently sensitive to detect the most restrictive isotope used and listed in Table R.2 for restricted areas and R.3 for unrestricted areas (e.g., 200 dpm/100 cm^2 for isotopes of iodine-131 in unrestricted areas). Removable contamination survey samples will be measured in a low-background area. The following areas and frequencies will be followed:
  - — Removable contamination surveys weekly for radiopharmaceutical elution, preparation, assay, and administration areas. If diagnostic administrations are occasionally made in patients' rooms (i.e., bone scan injections, Tc-99m heart agents, etc.), with special care taken to remove all paraphernalia, those rooms need not be surveyed.
  - — Removable contamination surveys monthly of laboratory areas where only small quantities of photon-emitting radioactive material are used (<200 microcuries at a time).
  - — Removable contamination surveys weekly for radionuclide storage and radionuclide waste storage areas.
- A radioactive source with a known amount of activity will be used to convert sample measurements (usually in cpm) to dpm.
- The area will be either decontaminated, shielded, or posted and restricted from use if it cannot be decontaminated. ***Note:*** *A report to NRC may be required pursuant to 10 CFR 30.50.*
- The RSO will be immediately notified of contamination levels in excess of the trigger levels. Trigger levels for restricted areas are presented in Table R-2. Contamination found in unrestricted areas and on personal clothing will be immediately decontaminated to background levels. When it is not possible to get to background levels, we will ensure that the amounts do not exceed the contamination levels listed in Table R-3.

Table R.2 Acceptable Surface Contamination Levels in Restricted Areas in dpm/100 cm^2.

Area, clothing, skin if indicated	P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, Y-90, In-111, I-123, I-125, I-131, Sm-153, Yb-169, Lu-177, Au-198	Cr-51, Co-57, Ga-67, Tc-99m, Hg-197, Tl-201
Restricted areas, protective clothing used only in restricted areas, skin	2000	20000

Table R.3 Acceptable Surface Contamination Levels in Unrestricted Areas in dpm/100 cm^2.

Nuclide[1]	Average[2, 3, 6]	Maximum[2, 4, 6]	Removable[2, 5, 6]
I-125, I-126, I-131, I-133, Sr-90	1,000	3,000	200
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except Sr-90 and others noted above.	5,000	15,000	1,000

[1] Where surface contamination by multiple nuclides exists, the limits established for each nuclide should apply independently.

[2] As used in this table, dpm means the rate of emission by radioactive material, as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.

[3] Measurements of average contaminant should not be averaged over more than 1 square meter. For objects of less surface area, the average should be derived for each such object.

[4] The maximum contamination level applies to an area of not more than 100 cm^2.

[5] The amount of removable radioactive material per 100 cm^2 of surface area should be determined by wiping that area with filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.

[6] The average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 0.2 millirad/hour at 1 centimeter and 1.0 millirad/hour at 1 centimeter, respectively, measured through not more than 7 milligrams per square centimeter of total absorber.

- When equipment or facilities that are potentially contaminated are to be released to unrestricted areas, the above table provides the maximum acceptable residual levels. To the extent practicable and consistent with the ALARA principle, it is appropriate to decontaminate to below these levels. Surface contamination surveys will be conducted for both removable and fixed contamination before these facilities or equipment are released from restricted to unrestricted use to ensure that they meet these limits.
- A standardized method for smear-testing of a relatively uniform area will be used to aid in comparing contamination at different times and places. A smear taken from an area of about 100 cm^2 is acceptable to indicate levels of removable contamination.

Alternate Survey Frequency

An alternate survey frequency is described below. The object is to determine how often to survey the laboratory. To do this, multiply the activity range for the appropriate group under LOW, MEDIUM, and HIGH survey frequency by the appropriate Modifying Factor to construct a new set of mCi ranges for LOW, MEDIUM, and HIGH survey frequency. For instance, if 30 millicuries of iodine-131 is used in the hot laboratory, the survey frequency for the hot laboratory would be daily; since the group for iodine-131 is Group 2, the survey frequency category for an activity of greater than 10 millicuries is high, and the modifying factor is 1.

Table R.4 Grouping of Radioisotopes for Alternate Survey Frequency.

Group 1	Group 1, excerpted from IAEA Safety Series 115, does not include radioisotopes traditionally used in medicine.
Group 2	Co-60 Sr-90 I-125 I-126 I-131 I-133 Cs-134 Cs-137 Eu-152 (13 y) Eu-154 Ir-192 T1-204
Group 3	C-14 F-18 Na-24 P-32 S-35 Cr-51 Fe-59 Co-57 Co-58 Se-75 Sr-85 Y-90 Mo-99 Tc-99 Rh-105 Pd-103 In-115m Sn-113 Sm-153 Eu-152 Eu-155 Gd-153 Dy-165 Yb-175 Lu-177 Au-198 Hg-197 Tl-201
Group 4	H-3 0-15 Rb-87 Tc-99m Rh-103m In-113m Xe-133 Cs-134m

Table R.5 Classification of Laboratories for Alternate Survey Frequency.

Survey Frequency Category			
Group	**Low**	**Medium**	**High**
1	<0.1 mCi	0.1 mCi to 1 mCi	>1 mCi
2	<1 mCi	1 mCi to 10 mCi	>10 mCi
3	<100 mCi	100 mCi to 1 Ci	>1 Ci
4	<10 Ci	10 Ci to 100 Ci	>100 Ci

Survey Frequency:

- Low – Not less than once a month;
- Medium – Not less than once per week;
- High – Not less than once per normal working day.

Proportional fractions are to be used for more than one isotope.

Table R.6 Modifying Factors for Alternate Survey Frequency.

Modifying Factors	Factors
Simple storage	x 100
Very simple wet operations (e.g., preparation of aliquots of stock solutions)	x 10
Normal chemical operations (e.g., analysis, simple chemical preparations)	x 1
Complex wet operations (e.g., multiple operations, or operations with complex glass apparatus)	x 0.1
Simple dry operations (e.g., manipulation of powders) and work with volatile radioactive compounds	x 0.1
Exposure of non-occupational persons (including patients)	x 0.1
Dry and dusty operations (e.g., grinding)	x 0.01

Survey Record Requirements

Each survey report will include the following:

- A diagram of the area surveyed;
- A list of items and equipment surveyed;
- Specific locations on the survey diagram where wipe tests were taken;
- Ambient radiation levels with appropriate units;
- Contamination levels with appropriate units;
- Make and model number of instruments used;
- Background levels;
- Name of the person making the evaluation and recording the results and date.

We will record contamination levels observed and procedures followed for incidents involving contamination of individuals. The record will include names of individuals involved, description of work activities, calculated dose, probable causes (including root causes), steps taken to reduce future incidents of contamination, times and dates, and the surveyor's signature.

Appendix S

Procedures for Developing, Maintaining, and Implementing Written Directives

Procedures for Developing, Maintaining, and Implementing Written Directives

This model provides acceptable procedures for administrations that require written directives. You may either adopt this model procedure or develop your own procedure to meet the requirements of 10 CFR 35.40 and 10 CFR 35.41.

Written Directive Procedures

This model provides guidance to licensees and applicants for developing, maintaining, and implementing procedures for administrations that require written directives (WD). This model does not restrict your use of other guidance in developing, implementing, and maintaining written procedures for administrations requiring a WD. Such procedures are to provide high confidence that the objectives specified in 10 CFR 35.41 will be met.

The WD must be prepared for any administration of I-131 sodium iodide greater than 1.11 MBq (30 μCi), any therapeutic dosage of a radiopharmaceutical, and any therapeutic dose of radiation from byproduct material. The WD must contain the information described in 10 CFR 35.40 and be retained in accordance with 10 CFR 35.2040.

Discussion

The administration of radioactive materials can be a complex process for many types of diagnostic and therapeutic procedures in nuclear medicine or radiation oncology departments. A number of individuals may be involved in the delivery process. For example, in an oncology department, when the AU prescribes a teletherapy treatment, the delivery process may involve a team of medical professionals such as an AMP, a dosimetrist, and a radiation therapist. Treatment planning may involve a number of measurements, calculations, computer-generated treatment plans, patient simulations, portal film verifications, and beam-modifying devices to deliver the prescribed dose. Therefore, instructions must be clearly communicated to the professional team members with constant attention devoted to detail during the treatment process. Complicated processes of this nature require good planning and clear, understandable procedures. To help ensure that all personnel involved in the treatment fully understand instructions in the WD or treatment plan, the licensee should instruct all workers to seek guidance if they do not understand how to carry out the WD. Specifically, workers should ask if they have any questions about what to do or how it should be done before administration, rather than continuing a procedure when there is any doubt. Licensees should also consider verification of WDs or treatment plans by at least one qualified person (e.g., an oncology physician, AMP, nuclear medicine technologist, or radiation therapist), preferably other than the individual who prepared the dose, the dosage, or the treatment plan.

The administration of radioactive materials can involve a number of treatment modalities, e.g., radiopharmaceutical therapy, teletherapy, brachytherapy, gamma stereotactic radiosurgery, and future emerging technologies. For each such modality for which 10 CFR 35.40 requires, or would require, a written directive (as defined in 10 CFR 35.2), the licensee shall develop, implement, and maintain written procedures for WDs to meet the requirements and/or objectives of 10 CFR 35.40, 35.41, and 10 CFR 35.63, outlined below:

- Have an authorized user date and sign a written directive prior to the administration that includes the information in 10 CFR 35.40(b), including the patient or human research subject's name;
- Verify the patient's or human research subject's identity prior to each administration;
- Verify that the administration is in accordance with the treatment plan, if applicable, and the written directive;
- Check both manual and computer-generated dose calculations;
- Verify that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical devices; and
- Determine and record the activity of the radiopharmaceutical dosage or radiation dose before medical use.

The following procedures are provided as assistance in meeting the above objectives.

Procedures for Any Therapeutic Dose or Dosage of a Radionuclide or Any Dosage of Quantities Greater than 30 Microcuries of Sodium Iodide I-131

We will develop, implement, and maintain the following procedures to meet the objectives of 10 CFR 35.40 and 10 CFR 35.41:

A. An AU must date and sign a WD prior to the administration of any dose or dosage.

B. Prior to administering a dose or dosage, the patient's or human research subject's identity will be positively verified as the individual named in the WD. Examples of positive patient identity verification include examining the patient's ID bracelet, hospital ID card, driver's license, or social security card. Asking or calling the patient's name does not constitute positive patient identity verification.

C. The specific details of the administration will be verified, including the dose or dosage, in accordance with the WD or treatment plan. All components of the WD (radionuclide, total dose or dosage, etc.) will be confirmed by the person administering the dose or dosage to verify agreement with the WD. Appropriate verification methods include: measuring the activity in the dose calibrator, checking the serial number of the sealed sources behind an appropriate shield, using color-coded sealed sources, or using clearly marked storage locations.

Additional Procedures for Sealed Therapeutic Sources and Devices Containing Sealed Therapeutic Sources

For sealed therapeutic sources and devices containing sealed therapeutic sources, we will develop, implement, and maintain the additional following procedures to meet the objectives of 10 CFR 35.40 and 10 CFR 35.41:

A. To ensure that the dose is delivered in accordance with the WD, the AU (and the neurosurgeon for GSR therapy) must date and sign (indicating approval of) the treatment plan that provides sufficient information and direction to meet the objectives of the WD.

B. For sealed sources inserted into the patient's body, radiographs or other comparable images (e.g., computerized tomography) will be used as the basis for verifying the position of the nonradioactive dummy sources and calculating the administered dose before administration. However, some brachytherapy procedures may require the use of various fixed geometry applicators (e.g., appliances or templates) to establish the location of the temporary sources and calculate the exposure time (or, equivalently, the total dose) required to administer the prescribed brachytherapy treatment. In these cases, radiographs or other comparable images may not be necessary, provided the position of the sources is known prior to insertion of the radioactive sources and calculation of the exposure time (or, equivalently, the total dose).

C. Dose calculations will be checked before administering the prescribed therapy dose. An AU or a qualified person under the supervision of an AU (e.g., an AMP, oncology physician, dosimetrist, or radiation therapist), preferably one who did not make the original calculations, will check the dose calculations. Methods for checking the calculations include the following:

   1. For computer-generated dose calculations, examining the computer printout to verify that correct input data for the patient was used in the calculations (e.g., source strength and positions).

   2. For computer-generated dose calculations entered into the therapy console, verifying correct transfer of data from the computer (e.g., channel numbers, source positions, and treatment times).

3. For manually-generated dose calculations, verifying:
    a. No arithmetic errors;
    b. Appropriate transfer of data from the WD, treatment plan, tables and graphs;
    c. Appropriate use of nomograms (when applicable); and
    d. Appropriate use of all pertinent data in the calculations.

    The therapy dose will be manually calculated to a single key point and the results compared to the computer-generated dose calculations. If the manual dose calculations are performed using computer-generated outputs (or vice versa), verify the correct output from one type of calculation (e.g., computer) to be used as an input in another type of calculation (e.g., manual). Parameters such as the transmission factors for wedges and applicators and the source strength of the sealed source used in the dose calculations will be checked.

D. After insertion of permanent implant brachytherapy sources, an AU will promptly record in the patient's chart or other appropriate record the actual number of radioactive sources implanted, any other information required by 10 CFR 35.40(b)(6), and sign or initial the record.

E. Acceptance testing will be performed by a qualified person (e.g., an AMP) on each treatment planning or dose calculating computer program that could be used for dose calculations. Acceptance testing will be performed before the first use of a treatment planning or dose calculating computer program for therapy dose calculations. Each treatment planning or dose calculating computer program will be assessed based on specific needs and applications. A check of the acceptance testing will also be performed after each source replacement or when spot check measurements indicate that the source output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for radioactive decay.

F. Independent checks on full calibration measurements will be performed. The independent check will include an output measurement for a single specified set of exposure conditions and will be performed within 30 days following the full calibration measurements. The independent check will be performed by either:

    1. An individual who did not perform the full calibration (the individual will meet the requirements specified in 10 CFR 35.51) using a dosimetry system other than the one that was used during the full calibration (the dosimetry system will meet the requirements specified in 10 CFR 35.630); or

    2. An AMP (or an oncology physician, dosimetrist, or radiation therapist who has been properly instructed) using a thermoluminescence dosimetry service available by mail that is designed for confirming therapy doses and that is accurate within 5%.

G. Full calibration measurements will include the determination of transmission factors for trays, wedges, applicators, etc. Transmission factors for other beam-modifying devices (e.g.,

nonrecastable blocks, recastable block material, bolus and compensator materials, and split-beam blocking devices) will be determined before the first medical use of the beam-modifying device and after replacement of the source.

H. For GSR, particular emphasis will be directed on verifying that the stereoscopic frame coordinates on the patient's skull match those of the treatment plan.

I. A physical measurement of the teletherapy output will be made under applicable conditions prior to administration of the first teletherapy fractional dose, if the patient's treatment plan includes: (1) field sizes or treatment distances that fall outside the range of those measured in the most recent full calibration; or (2) transmission factors for beam-modifying devices (except nonrecastable and recastable blocks, bolus and compensator materials, and split-beam blocking devices) not measured in the most recent full calibration measurement.

J. A weekly chart check will be performed by a qualified person under the supervision of an AU (e.g., an AMP, dosimetrist, oncology physician, or radiation therapist) to detect mistakes (e.g., arithmetic errors, miscalculations, or incorrect transfer of data) that may have occurred in the daily and cumulative dose administrations from all treatment fields or in connection with any changes in the WD or treatment plan.

K. Treatment planning computer systems using removable media to store each patient's treatment parameters for direct transfer to the treatment system will have each card labeled with the corresponding patient's name and identification number. Such media may be reused (and must be relabeled) in accordance with the manufacturer's instructions.

Review of Administrations Requiring a Written Directive

In accordance with 10 CFR 35.41, we will develop, implement, and maintain procedures to conduct periodic reviews of each applicable program area, e.g., radiopharmaceutical therapy, high-dose-rate brachytherapy, implant brachytherapy, teletherapy, gamma stereotactic radiosurgery, and emerging technologies. The number of patient cases to be sampled will be based on the principles of statistical acceptance sampling and will represent each treatment modality performed in the institution, e.g., radiopharmaceutical, teletherapy, brachytherapy and gamma stereotactic radiosurgery.

If feasible, the persons conducting the review will not review their own work. If this is not possible, two people will work together as a team to conduct the review of that work. We will regularly review the findings of the periodic reviews to ensure that the procedures for administrations requiring a WD are effective.

A determination will be made as to whether the administered radiopharmaceutical dosage or radiation dose was in accordance with the WD or treatment plan, as applicable. For each patient case reviewed, deviations from the WD, the cause of each deviation, and the action required to prevent recurrence will be identified.

Reports of Medical Events

We will notify by telephone the NRC Operations Center[1] no later than the next calendar day after discovery of the medical event and submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 within 15 days after the discovery of the medical event, as required by 10 CFR 35.3045. We will also notify the referring physician and the patient as required by 10 CFR 35.3045.

[1] The commercial telephone number of the NRC Operations Center is (301) 951-0550. The Center will accept collect calls.

Appendix T

Model Procedures for Safe Use of Licensed Material

Model Procedures for Safe Use of Licensed Material

This model provides acceptable procedures for safe use of licensed material. You may either adopt this model procedure or develop your own procedure to meet the requirements of 10 CFR 20.1101, 10 CFR 20.1301, and 10 CFR 35.69.

- Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.
- Wear disposable gloves at all times while handling radioactive materials.
- Either after each procedure or before leaving the area, monitor your hands for contamination in a low-background area using an appropriate survey instrument.
- Use syringe shields for reconstitution of radiopharmaceutical kits and administration of radiopharmaceuticals to patients, except when their use is contraindicated (e.g., recessed veins, infants). In these exceptional cases, use other protective methods, such as remote delivery of the dose (e.g., use a butterfly needle.)
- Do not eat, store food, drink, smoke, or apply cosmetics in any area where licensed material is stored or used.
- Wear personnel monitoring devices, if required, at all times while in areas where radioactive materials are used or stored. These devices shall be worn as prescribed by the RSO. When not being worn to monitor occupational exposures, personnel monitoring devices shall be stored in the work place in a designated low-background area.
- Wear extremity dosimeters, if required, when handling radioactive material.
- Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
- Never pipette by mouth.
- Wipe-test unsealed byproduct material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate the area.
- Survey with a radiation detection survey meter all areas of licensed material use, including the generator storage, kit preparation, and injection areas daily for contamination. If necessary, decontaminate the area. Areas used to prepare and administer therapy quantities of radiopharmaceuticals must be surveyed daily in accordance with 10 CFR 35.70 (except when administering therapy dosages in patients' rooms when patients are confined).
- Store radioactive solutions in shielded containers that are clearly labeled.
- Radiopharmaceutical multidose diagnostic and therapy vials must be labeled in accordance with 10 CFR 35.69 and 10 CFR 20.1904. Mark the label with the radionuclide, the activity, the date for which the activity is estimated, and the kind of materials (i.e., radiopharmaceutical).

- Syringes and unit dosages must be labeled in accordance with 10 CFR 35.69 and 10 CFR 20.1904. Mark the label with the radionuclide, the activity, the date for which the activity is estimated, and the kind of materials (i.e., radiopharmaceutical). If the container is holding less than the quantities listed in Appendix C to Part 20, the syringe or vial need only be labeled to identify the radioactive drug (10 CFR 35.69). To avoid mistaking patient dosages, label the syringe with the type of study and the patient's name.
- For prepared dosages, assay each patient dosage in the dose calibrator (or instrument) before administering it (10 CFR 35.63).
- Do not use a dosage if it does not fall within the prescribed dosage range or if it varies more than ±20% from the prescribed dosage, except as approved by an authorized user.
- When measuring the dosage, you need not consider the radioactivity that adheres to the syringe wall or remains in the needle.
- Check the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administering. If the prescribed dosage requires a written directive, the patient's identity must be verified and the administration must be in accordance with the written directive (10 CFR 35.41).
- Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.
- Secure all licensed material when not under the constant surveillance and immediate control of the authorized user(s).

Appendix U

Release of Patients or Human Research Subjects Administered Radioactive Materials

Release of Patients or Human Research Subjects Administered Radioactive Materials

Section 35.75, "Release of Individuals Containing Unsealed Byproduct Material or Implants Containing Byproduct Material," of 10 CFR Part 35, "Medical Use of Byproduct Material," permits a licensee to "authorize the release from its control any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem)."

In this appendix, the individual or human research subject to whom the radioactive material has been administered is called the "patient."

Release Equation

The activities at which patients could be released were calculated by using, as a starting point, the method discussed in the National Council on Radiation Protection and Measurements (NCRP) Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides."

NCRP Report No. 37 uses the following equation to calculate the exposure until time *t* at a distance *r* from the patient:

Equation U.1:
$$D(t) = \frac{34.6\ \Gamma\ Q_0\ T_P\ (1 - e^{-0.693t/T_P})}{r^2}$$

Where:

D(t)	=	Accumulated exposure at time t, in roentgens
34.6	=	Conversion factor of 24 hrs/day times the total integration of decay (1.44)
Γ	=	Specific gamma ray constant for a point source, R/mCi-hr at 1 cm
Q_0	=	Initial activity of the point source in millicuries, at the time of the release
T_p	=	Physical half-life in days
r	=	Distance from the point source to the point of interest, in centimeters
t	=	Exposure time in days.

This appendix uses the NCRP equation (Equation U.1) in the following manner to calculate the activities at which patients may be released.

- The dose to an individual likely to receive the highest dose from exposure to the patient is taken to be the dose to total decay. Therefore, $(1\text{-}e^{-0.693t/Tp})$ is set equal to 1.
- It is assumed that 1 roentgen is equal to 10 millisieverts (1 rem).
- The exposure-rate constants and physical half-lives for radionuclides typically used in nuclear medicine and brachytherapy procedures are given in Supplement A to this appendix.
- Default activities at which patients may be released are calculated using the physical half-lives of the radionuclides and do not account for the biological half-lives of the radionuclides.
- When release is based on biological elimination (i.e., the effective half-life) rather than just the physical half-life of the radionuclide, Equation U.1 is modified to account for the uptake and retention of the radionuclide by the patient, as discussed in Supplement B.2.
- For radionuclides with a physical half-life greater than 1 day and no consideration of biological elimination, it is assumed that the individual likely to receive the highest dose from exposure to the patient would receive a dose of 25% of the dose to total decay (0.25 in Equation U.2), at a distance of 1 meter. Selection of 25% of the dose to total decay at 1 meter for estimating the dose is based on measurements discussed in the supporting regulatory analysis that indicate the dose calculated using an occupancy factor, E, of 25% at 1 meter is conservative in most normal situations.
- For radionuclides with a physical half-life less than or equal to 1 day, it is difficult to justify an occupancy factor of 0.25, because relatively long-term averaging of behavior cannot be assumed. Under this situation, occupancy factors from 0.75 to 1.0 may be more appropriate.

Thus, for radionuclides with a physical half-life greater than 1 day:

Equation U.2: $$D(\infty) = \frac{34.6\ \Gamma\ Q_0\ T_p\ (0.25)}{(100\ cm)^2}$$

For radionuclides with a physical half-life less than or equal to 1 day, and if an occupancy factor of 1.0 is used:

Equation U.3: $$D(\infty) = \frac{34.6\ \Gamma\ Q_0\ T_p\ (1)}{(100\ cm)^2}$$

Equations U.2 and U.3 calculate the dose from external exposure to gamma radiation. These equations do not include the dose from internal intake by household members and members of the public, because the dose from intake by other individuals is expected to be small for most radiopharmaceuticals (less than a few percent), relative to the external gamma dose (see "Internal Dose,"of Supplement B). Further, the equations above do not apply to the dose to breast-feeding infants or children who continue to breast-feed. Patients who are breast-feeding an infant or child must be considered separately, as discussed in Item U.1.1, "Release of Patients Based on Administered Activity."

U.1 Release Criteria

Licensees should use one of the following options to release a patient to whom unsealed byproduct material or implants containing byproduct material have been administered in accordance with regulatory requirements.

U.1.1 Release of Patients Based on Administered Activity

In compliance with the dose limit in 10 CFR 35.75(a), licensees may release patients from licensee control if the activity administered is no greater than the activity in Column 1 of Table U.1. The activities in Table U.1 are based on a total effective dose equivalent of 5 millisieverts (0.5 rem) to an individual using the following conservative assumptions:

- Administered activity;
- Physical half-life;
- Occupancy factor of 0.25 at 1 meter for physical half-lives greater than 1 day and, to be conservative, an occupancy factor of 1 at 1 meter for physical half-lives less than or equal to 1 day; and
- No shielding by tissue.

The total effective dose equivalent is approximately equal to the external dose because the internal dose is a small fraction of the external dose (see Section B.3, "Internal Dose," of Supplement B). In this case, no record of the release of the patient is required unless the patient is breast-feeding an infant or child, as discussed in Item U.3.2, "Records of Instructions for Breast-Feeding Patients." The licensee may demonstrate compliance by using the records of activity that are already required by 10 CFR 35.40 and 35.63.

If the activity administered exceeds the activity in Column 1 of Table U.1, the licensee may release the patient when the activity has decayed to the activity in Column 1 of Table U.1. In this case, 10 CFR 35.75(c) requires a record because the patient's release is based on the retained activity rather than the administered activity. The activities in Column 1 of Table U.1 were

calculated using either Equation U.2 or U.3, depending on the physical half-life of the radionuclide.

If a radionuclide that is not listed in Table U.1 is administered, the licensee can demonstrate compliance with the regulation by maintaining, for NRC inspection, calculation of the release activity that corresponds to the dose limit of 5 millisieverts (0.5 rem). Equation U.2 or U.3 may be used, as appropriate, to calculate the activity Q corresponding to 5 millisieverts (0.5 rem).

The release activities in Column 1 of Table U.1 do not include consideration of the dose to a breast-feeding infant or child from ingestion of radiopharmaceuticals contained in the patient's breast milk. When the patient is breast-feeding an infant or child, the activities in Column 1 of Table U.1 are not applicable to the infant or child. In this case, it may be necessary to give instructions as described in Items U.2.2 and U.2.3 as a condition for release. If failure to interrupt or discontinue could result in a dose to the breast-feeding infant or child in excess of 5 millisieverts (0.5 rem), a record that instructions were provided is required by 10 CFR 35.75(d).

U.1.2 Release of Patients Based on Measured Dose Rate

Licensees may release patients to whom radionuclides have been administered in amounts greater than the activities listed in Column 1 of Table U.1, provided the measured dose rate at 1 meter (from the surface of the patient) is no greater than the value in Column 2 of Table U.1 for that radionuclide. In this case, however, 10 CFR 35.75(c) requires a record because the release is based on considering shielding by tissue.

If a radionuclide not listed in Table U.1 is administered and the licensee chooses to release a patient based on the measured dose rate, the licensee should first calculate a dose rate that corresponds to the 5 millisievert (0.5 rem) dose limit. If the measured dose rate at 1 meter is no greater than the calculated dose rate, the patient may be released. A record of the release is required by 10 CFR 35.75(c). The dose rate at 1 meter may be calculated from Equation U.2 or U.3, as appropriate, because the dose rate at 1 meter is equal to $\Gamma Q/10{,}000$ cm^2.

U.1.3 Release of Patients Based on Patient-Specific Dose Calculations

Licensees may release patients based on dose calculations using patient-specific parameters. With this method, based on 10 CFR 35.75(a), the licensee must calculate the maximum likely dose to an individual exposed to the patient on a case-by-case basis. If the calculated maximum likely dose to an individual is no greater than 5 millisieverts (0.5 rem), the patient may be released. Using this method, licensees may be able to release patients with activities greater than those listed in Column 1 of Table U.1 by taking into account the effective half-life of the radioactive material and other factors that may be relevant to the particular case. In this case, a record of the release is required by 10 CFR 35.75(c). If the dose calculation considered retained

activity, an occupancy factor less than 0.25 at 1 meter, effective half-life, or shielding by tissue, a record of the basis for the release is required by 10 CFR 35.75(c).

Supplement B contains procedures for performing patient-specific dose calculations, and it describes how various factors may be considered in the calculations.

Table U.1 Activities and Dose Rates for Authorizing Patient Release†.

Radionuclide	COLUMN 1 Activity at or Below Which Patients May Be Released		COLUMN 2 Dose Rate at 1 Meter, at or Below Which Patients May Be Released*	
	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)
Ag-111	19	520	0.08	8
Au-198	3.5	93	0.21	21
Cr-51	4.8	130	0.02	2
Cu-64	8.4	230	0.27	27
Cu-67	14	390	0.22	22
Ga-67	8.7	240	0.18	18
I-123	6.0	160	0.26	26
I-125	0.25	7	0.01	1
I-125 implant	0.33	9	0.01	1
I-131	1.2	33	0.07	7
In-111	2.4	64	0.2	20
Ir-192 implant	0.074	2	0.008	0.8
P-32	**	**	**	**
Pd-103 implant	1.5	40	0.03	3
Re-186	28	770	0.15	15
Re-188	29	790	0.2	20
Sc-47	11	310	0.17	17
Se-75	0.089	2	0.005	0.5
Sm-153	26	700	0.3	30
Sn-117m	1.1	29	0.04	4
Sr-89	**	**	**	**
Tc-99m	28	760	0.58	58

Radionuclide	COLUMN 1 Activity at or Below Which Patients May Be Released		COLUMN 2 Dose Rate at 1 Meter, at or Below Which Patients May Be Released*	
	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)
Tl-201	16	430	0.19	19
Y-90	**	**	**	**
Yb-169	0.37	10	0.02	2

† The activity values were computed based on 5 millisieverts (0.5 rem) total effective dose equivalent.

* If the release is based on the dose rate at 1 meter in Column 2, the licensee must maintain a record as required by 10 CFR 35.75(c), because the measurement includes shielding by tissue. See Item U.3.1, "Records of Release," for information on records.

** Activity and dose rate limits are not applicable in this case because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic purposes.

Notes: The millicurie values were calculated using Equations U.2 or U.3 and the physical half-life. The gigabecquerel values were calculated using the millicurie values and the conversion factor from millicuries to gigabecquerels. The dose rate values are calculated using the millicurie values and the exposure rate constants.

In general, the values are rounded to two significant figures; however, values less than 0.37 gigabecquerel (10 millicuries) or 0.1 millisievert (10 millirems) per hour are rounded to one significant figure. Details of the calculations are provided in NUREG-1492.

Although non-byproduct materials are not regulated by NRC, information on non-byproduct material is included for the convenience of the licensee.

Agreement State regulations may vary. Agreement State licensees should check with their State regulations before using these values.

U.2 Instructions

This Section provides acceptable instructions for release of patients administered radioactive materials. You may either adopt these model instructions or develop your own instructions to meet the requirements of 10 CFR 35.75.

U.2.1 Activities and Dose Rates Requiring Instructions

Based on 10 CFR 35.75(b), for some administrations the released patients must be given instructions, including written instructions, on how to maintain doses to other individuals ALARA after the patients are released.[1] Column 1 of Table U.2 provides the activity above which instructions must be given to patients. Column 2 provides corresponding dose rates at 1

[1] NRC does not intend to enforce patient compliance with the instructions nor is it the licensee's responsibility to do so.

meter, based on the activities in Column 1. The activities or dose rates in Table U.2 may be used for determining when instructions must be given. If the patient is breast-feeding an infant or child, additional instructions may be necessary (see Item U.2.2, "Additional Instructions for Release of Patients Who Could be Breast-Feeding After Release").

When patient-specific calculations (as described in Supplement B) are used, instructions must be provided if the calculation indicates a dose greater than 1 millisievert (0.1 rem).

If a radionuclide not listed in Table U.2 is administered, the licensee may calculate the activity or dose rate that corresponds to 1 millisievert (0.1 rem). Equation U.2 or U.3, as appropriate, may be used.

U.2.2 Additional Instructions for Release of Patients Who Could Be Breast-Feeding After Release

The requirement in 10 CFR 35.75(b) that a licensee provide instructions on the discontinuation or the interruption period of breast-feeding, and the consequences of failing to follow the recommendation, presumes that the licensee will inquire, as appropriate, regarding the breast-feeding status of the patient.[1] The purpose of the instructions (e.g., on interruption or discontinuation) is to permit licensees to release a patient who could be breast-feeding an infant or child when the dose to the infant or child could exceed 5 millisieverts (0.5 rem) if there is no interruption of breast-feeding.

If the patient could be breast-feeding an infant or child after release, and if a radiopharmaceutical with an activity above the value stated in Column 1 of Table U.3 was administered to the patient, the licensee must give the patient instructions on the discontinuation or interruption period for breast-feeding and the consequences of failing to follow the recommendation. The patient should also be informed if there would be no consequences to the breast-feeding infant or child. Table U.3 also provides recommendations for interrupting or discontinuing breast-feeding to minimize the dose to below 1 millisievert (0.1 rem) if the patient has received certain radiopharmaceutical doses. The radiopharmaceuticals listed in Table U.3 are commonly used in medical diagnosis and treatment.

If a radiopharmaceutical not listed in Table U.3 is administered to a patient who could be breast-feeding, the licensee should evaluate whether instructions or records (or both) are required. If information on the excretion of the radiopharmaceutical is not available, an acceptable method is to assume that 50% of the administered activity is excreted in the breast milk. The dose to the infant or child can be calculated by using the dose conversion factors given for a newborn infant by Stabin.

U.2.3 Content of Instructions

The instructions should be specific to the type of treatment given, such as permanent implants or radioiodine for hyperthyroidism or thyroid carcinoma, and they may include additional information for individual situations; however, the instructions should not interfere with or contradict the best medical judgment of physicians. The instructions may include the name of a knowledgeable contact person and that person's telephone number, in case the patient has any questions. Additional instructions appropriate for each modality, as shown in examples below, may be provided (refer to U.2.3.1 and U.2.3.2).

Table U.2 Activities and Dose Rates Above Which Instructions Should Be Given When Authorizing Patient Release*.

Radionuclide	COLUMN 1 Activity Above Which Instructions Are Required		COLUMN 2 Dose Rate at 1 Meter Above Which Instructions Are Required	
	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)
Ag-111	3.8	100	0.02	2
Au-198	0.69	19	0.04	4
Cr-51	0.96	26	0.004	0.4
Cu-64	1.7	45	0.05	5
Cu-67	2.9	77	0.04	4
Ga-67	1.7	47	0.04	4
I-123	1.2	33	0.05	5
I-125	0.05	1	0.002	0.2
I-125 implant	0.074	2	0.002	0.2
I-131	0.24	7	0.02	2
In-111	0.47	13	0.04	4
Ir-192 implant	0.011	0.3	0.002	0.2
P-32	**	**	**	**
Pd-103 implant	0.3	8	0.007	0.7
Re-186	5.7	150	0.03	3
Re-188	5.8	160	0.04	4
Sc-47	2.3	62	0.03	3
Se-75	0.018	0.5	0.001	0.1
Sm-153	5.2	140	0.06	6

Radionuclide	COLUMN 1 Activity Above Which Instructions Are Required		COLUMN 2 Dose Rate at 1 Meter Above Which Instructions Are Required	
	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)
Sn-117m	0.21	6	0.009	0.9
Sr-89	**	**	**	**
Tc-99m	5.6	150	0.12	12
Tl-201	3.1	85	0.04	4
Y-90	**	**	**	**
Yb-169	0.073	2	0.004	0.4

* The activity values were computed based on 1 millisievert (0.1 rem) total effective dose equivalent.

** Activity and dose rate limits are not applicable in this case because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic purposes .

Notes: The millicurie values were calculated using Equations U.2 or U.3 and the physical half-life. The gigabecquerel values were calculated based on millicurie values and the conversion factor from millicuries to gigabecquerels. The dose rate values were calculated based on millicurie values and exposure rate constants.

In general, values are rounded to two significant figures; however, values less than 0.37 gigabecquerel (10 millicuries) or 0.1 millisievert (10 millirems) per hour are rounded to one significant figure. Details of the calculations are provided in NUREG-1492.

Although non-byproduct materials are not regulated by NRC, information on non-byproduct material is included for the convenience of the licensee.

Agreement State regulations may vary. Agreement State licensees should check with their state regulations before using these values.

Table U.3 Activities of Radiopharmaceuticals that Require Instructions and Records When Administered to Patients Who are Breast-Feeding an Infant or Child.

Radionuclide	COLUMN 1 Activity Above Which Instructions Are Required		COLUMN 2 Activity Above Which a Record is Required		COLUMN 3 Examples of Recommended Duration of Interruption of Breast-Feeding
	(Mbq)	(mCi)	(Mbq)	(mCi)	
I-131 NaI	0.01	0.0004	0.07	0.002	Complete cessation (for this infant or child)
I-123 NaI	20	0.5	100	3	
I-123 OIH	100	4	700	20	
I-123 MIBG	70	2	400	10	24 hours for 370 Mbq (10 mCi) 12 hours for 150 MBq (4 mCi)
I-125 OIH	3	0.08	10	0.4	
I-131 OIH	10	0.30	60	1.5	
Tc-99m DTPA	1000	30	6000	150	
Tc-99m MAA	50	1.3	200	6.5	12.6 hours for 150 Mbq (4 mCi)
Tc-99m Pertechnetate	100	3	600	15	24 hours for 1,100 Mbq (30 mCi) 12 hours for 440 Mbq (12 mCi)
Tc-99m DISIDA	1000	30	6000	150	
Tc-99m Glucoheptonate	1000	30	6000	170	
Tc-99m MIBI	1000	30	6000	150	
Tc-99m MDP	1000	30	6000	150	
Tc-99m PYP	900	25	4000	120	
Tc-99m Red Blood Cell *In Vivo* Labeling	400	10	2000	50	6 hours for 740 Mbq (20 mCi)
Tc-99m Red Blood Cell *In Vitro* Labeling	1000	30	6000	150	

Radionuclide	COLUMN 1 Activity Above Which Instructions Are Required		COLUMN 2 Activity Above Which a Record is Required		COLUMN 3 Examples of Recommended Duration of Interruption of Breast-Feeding
	(Mbq)	(mCi)	(Mbq)	(mCi)	
Tc-99m Sulphur Colloid	300	7	1000	35	6 hours for 440 MBq (12 mCi)
Tc-99m DTPA Aerosol	1000	30	6000	150	
Tc-99m MAG3	1000	30	6000	150	
Tc-99m White Blood Cells	100	4	600	15	24 hours for 1,100 MBq (30 mCi) 12 hours for 440 MBq (12 mCi)
Ga-67 Citrate	1	0.04	7	0.2	1 month for 150 MBq (4 mCi) 2 weeks for 50 MBq (1.3 mCi) 1 week for 7 MBq (0.2 mCi)
Cr-51 EDTA	60	1.6	300	8	
In-111 White Blood Cells	10	0.2	40	1	1 week for 20 MBq (0.5 mCi)
Tl-201 Chloride	40	1	200	5	2 weeks for 110 MBq (3 mCi)

* The duration of interruption of breast-feeding is selected to reduce the maximum dose to a newborn infant to less than 1 millisievert (0.1 rem), although the regulatory limit is 5 millisieverts (0.5 rem). The actual doses that would be received by most infants would be far below 1 millisievert (0.1 rem). Of course, the physician may use discretion in the recommendation, increasing or decreasing the duration of interruption.

Notes: Activities are rounded to one significant figure, except when it was considered appropriate to use two significant figures. Details of the calculations are shown in NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material."

If there is no recommendation in Column 3 of this table, the maximum activity normally administered is below the activities that require instructions on interruption or discontinuation of breast-feeding.

Although non-byproduct materials are not regulated by NRC, information on non-byproduct material is included for the convenience of the licensee. Agreement State regulations may vary.

Agreement State licensees should check with their State regulations before using these values.

U.2.3.1 Instructions Regarding Radiopharmaceutical Administrations

For procedures involving radiopharmaceuticals, additional instructions may include the following:

- Maintaining distance from other persons, including separate sleeping arrangements.
- Minimizing time in public places (e.g., public transportation, grocery stores, shopping centers, theaters, restaurants, sporting events).
- Precautions to reduce the spread of radioactive contamination.
- The length of time each of the precautions should be in effect.

The Society of Nuclear Medicine published a pamphlet in 1987 that provides information for patients receiving treatment with radioiodine. This pamphlet was prepared jointly by the Society of Nuclear Medicine and NRC. The pamphlet contains blanks for the physician to fill in the length of time that each instruction should be followed. Although this pamphlet was written for the release of patients to whom less than 1,110 megabecquerels (30 millicuries) of iodine-131 had been administered, NRC still considers the instructions in this pamphlet to be an acceptable method for meeting the requirements of 10 CFR 35.75(b), provided the times filled in the blanks are appropriate for the activity and the medical condition.

If additional instructions are required because the patient is breast-feeding, the instructions should include appropriate recommendations on whether to interrupt breast-feeding, the length of time to interrupt breast-feeding, or, if necessary, the discontinuation of breast-feeding. The instructions should include information on the consequences of failure to follow the recommendation to interrupt or discontinue breast-feeding. The consequences should be explained so that the patient will understand that, in some cases, breast-feeding after an administration of certain radionuclides should be avoided. For example, a consequence of procedures involving iodine-131 is that continued breast-feeding could harm the infant's or child's thyroid. Most diagnostic procedures involve radionuclides other than radioiodine and there would be no consequences; guidance should simply address avoiding any unnecessary radiation exposure to the infant or child from breast-feeding. If the Society of Nuclear Medicine's pamphlet is given at release to a patient who is breast-feeding an infant or child, the pamphlet should be supplemented with information specified in 10 CFR 35.75(b)(1) and (2).

The requirement of 10 CFR 35.75(b) regarding written instructions to patients who could be breast-feeding an infant or child does not in any way interfere with the discretion and judgment of the physician in specifying the detailed instructions and recommendations.

U.2.3.2 Instructions Regarding Implants

For patients who have received implants, additional instructions may include the following:

A small radioactive source has been placed (implanted) inside your body. The source is actually many small metallic pellets or seeds, which are each about 1/3 to 1/4 of an inch long, similar in size and shape to a grain of rice. To minimize exposure to radiation to others from the source inside your body, you should do the following for_____days.

- Stay at a distance of _____ feet from _____.
- Maintain separate sleeping arrangements.
- Minimize time with children and pregnant women.
- Do not hold or cuddle children.
- Avoid public transportation.
- Examine any bandages or linens that come into contact with the implant site for any pellets or seeds that may have come out of the implant site.
- If you find a seed or pellet that falls out:
  - — Do not handle it with your fingers. Use something like a spoon or tweezers to place it in a jar or other container that you can close with a lid.
  - — Place the container with the seed or pellet in a location away from people.
  - — Notify _____ at telephone number _____ .

U.3 Records

U.3.1 Records of Release

There is no requirement for recordkeeping on the release of patients who were released in accordance with Column 1 of Table U.1; however, if the release of the patient is based on a dose calculation that considered retained activity, an occupancy factor less than 0.25 at 1 meter, effective half-life, or shielding by tissue, a record of the basis for the release is required by 10 CFR 35.75(c). This record should include the patient identifier (in a way that ensures that confidential patient information is not traceable or attributable to a specific patient), the radioactive material administered, the administered activity, and the date of the administration. In addition, depending on the basis for release, records should include the following information:

- **For Immediate Release of a Patient Based on a Patient-Specific Calculation:** The equation used, including the patient-specific factors and their bases that were used in

calculating the dose to the person exposed to the patient, and the calculated dose. The patient-specific factors (see Supplement B of this appendix) include the effective half-life and uptake fraction for each component of the biokinetic model, the time that the physical half-life was assumed to apply to retention, and the occupancy factor. The basis for selecting each of these values should be included in the record.

- **For Immediate Release of a Patient Based on Measured Dose Rate:** The results of the measurement, the specific survey instrument used, and the name of the individual performing the survey.
- **For Delayed Release of a Patient Based on Radioactive Decay Calculation:** The time of the administration, date and time of release, and the results of the decay calculation.
- **For Delayed Release of a Patient Based on Measured Dose Rate:** The results of the survey meter measurement, the specific survey instrument used, and the name of the individual performing the survey.

In some situations, a calculation may be case-specific for a class of patients who all have the same patient-specific factors. In this case, the record for a particular patient's release may reference the calculation for the class of patients.

Records, as required by 10 CFR 35.75(c), should be kept in a manner that ensures the patient's confidentiality, that is, the records should not contain the patient's name or any other information that could lead to identification of the patient. These recordkeeping requirements may also be used to verify that licensees have proper procedures in place for assessing potential third-party exposure associated with and arising from exposure to patients who were administered radioactive material.

U.3.2 Records of Instructions for Breast-Feeding Patients

If failure to interrupt or discontinue breast-feeding could result in a dose to the infant or child in excess of 5 millisieverts (0.5 rem), a record that instructions were provided is required by 10 CFR 35.75(d). Column 2 of Table U.3 states, for the radiopharmaceuticals commonly used in medical diagnosis and treatment, the activities that would require such records when administered to patients who are breast-feeding.

The record should include the patient's identifier (in a way that ensures that confidential patient information is not traceable or attributable to a specific patient), the radiopharmaceutical administered, the administered activity, the date of the administration, and whether instructions were provided to the patient who could be breast-feeding an infant or child.

U.4 Summary Table

Table U.4 summarizes the criteria for releasing patients and the requirements for providing instructions and maintaining records.

Table U.4 Summary of Release Criteria, Required Instructions to Patients, and Records to Be Maintained.

Patient Group	Basis for Release	Criteria for Release	Instructions Needed?	Release Records Required?
All patients, including patients who are breast-feeding an infant or child	Administered activity	Administered activity ≤Column 1 of Table U.1	Yes, if administered activity > Column 1 of Table U.2	No
	Retained activity	Retained activity ≤Column 1 of Table U.1	Yes, if retained activity > Column 1 of Table U.2	Yes
	Measured dose rate	Measured dose rate ≤Column 2 of Table U.1	Yes, if dose rate > Column 2 of Table U.2	Yes
	Patient-specific calculations	Calculated dose ≤5 mSv (0.5 rem)	Yes, if calculated dose > 1 mSv (0.1 rem)	Yes
Patients who are breast-feeding an infant or child	All of the above bases for release		Additional instructions required if: Administered activity > Column 1 of Table U.3 **OR** Licensee calculated dose from breast-feeding >1 mSv (0.1 rem) to the infant or child	Records that instructions were provided are required if: Administered activity > Column 2 of Table U.3 **OR** Licensee calculated dose from continued breast-feeding > 5 mSv (0.5 rem) to the infant or child

Implementation

The purpose of this section is to provide information to licensees and applicants regarding the NRC staff's plans for using this appendix. Except in those cases in which a licensee proposes an acceptable alternative method for complying with 10 CFR 35.75, the methods described in this appendix will be used in the evaluation of a licensee's compliance with 10 CFR 35.75.

References

National Council on Radiation Protection and Measurements (NCRP), "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," NCRP Report No. 37, October 1, 1970. (Available for sale from the NCRP, 7910 Woodmont Avenue, Suite 800, Bethesda, MD 20814-3095.)

S. Schneider and S. A. McGuire, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," NUREG-1492 (Final Report), NRC, February 1997.

M. Stabin, "Internal Dosimetry in Pediatric Nuclear Medicine," in *Pediatric Nuclear Medicine*, edited by S. Treves, Springer Verlag, New York, 1995.

"Guidelines for Patients Receiving Radioiodine Treatment," *Society of Nuclear Medicine*, 1987. This pamphlet may be obtained from the Society of Nuclear Medicine, 136 Madison Avenue, New York, NY 10016-6760.

Supplement A

Table U.5 Half-Lives and Exposure Rate Constants of Radionuclides Used in Medicine.

Radionuclide[1]	Physical Half-Life (days)[2]	Exposure Rate Constant[3] (R/mCi-h at 1 cm)
Ag-111	7.45	0.150
Au-198	2.696	2.3
Cr-51	27.704	0.16
Cu-64	0.529	1.2
Cu-67	2.578	0.58
Ga-67	3.261	0.753
I-123	0.55	1.61
I-125	60.14	1.42
I-125 implant	60.14	1.11[4]
I-131	8.04	2.2
In-111	2.83	3.21
Ir-192 implant	74.02	4.59[4]
P-32	14.29	NA[6]
Pd-103 implant	16.96	0.86[5]
Re-186	3.777	0.2
Re-188	0.708	0.26
Sc-47	3.351	0.56
Se-75	119.8	2.0
Sm-153	1.946	0.425
Sn-117m	13.61	1.48
Sr-89	50.5	NA[6]
Tc-99m	0.251	0.756
Tl-201	3.044	0.447

Radionuclide[1]	Physical Half-Life (days)[2]	Exposure Rate Constant[3] (R/mCi-h at 1 cm)
Yb-169	32.01	1.83
Y-90	2.67	NA[6]
Yb-169	32.01	1.83

[1] Although non-byproduct materials are not regulated by NRC, information on non-byproduct material is included for the convenience of the licensee.

[2] K.F. Eckerman, A.B. Wolbarst, and A.C.B. Richardson, "Federal Guidance Report No. 11, Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion," Report No. EPA-520/1-88-020, Office of Radiation Programs, U.S. Environmental Protection Agency, Washington, DC, 1988.

[3] Values for the exposure rate constant for Au-198, Cr-51, Cu-64, I-131, Sc-47, and Se-75 were taken from the *Radiological Health Handbook*, U.S. Department of Health, Education, and Welfare, pg. 135, 1970. For Cu-67, I-123, In-111, Re-186, and Re-188, the values for the exposure rate constant were taken from D.E. Barber, J.W. Baum, and C.B. Meinhold, "Radiation Safety Issues Related to Radiolabeled Antibodies," NUREG/CR-4444, U.S. NRC, Washington, DC, 1991. For Ag-111, Ga-67, I-125, Sm-153, Sn-117m, Tc-99m, Tl-201, and Yb-169, the exposure rate constants were calculated because the published values for these radionuclides were an approximation, presented as a range, or varied from one reference to another. Details of the calculation of the exposure rate constants are shown in Table A.2 of Appendix A to NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," U.S. NRC, February 1997.

[4] R. Nath, A.S. Meigooni, and J.A. Meli, "Dosimetry on Transverse Axes of ^{125}I and ^{192}Ir Interstitial Brachytherapy Sources," Medical Physics, Volume 17, Number 6, November/December 1990. The exposure rate constant given is a measured value averaged for several source models and takes into account the attenuation of gamma rays within the implant capsule itself.

[5] A.S. Meigooni, S. Sabnis, R. Nath, "Dosimetry of Palladium-103 Brachytherapy Sources for Permanent Implants," *Endocurietherapy Hyperthermia Oncology*, Volume 6, April 1990. The exposure rate constant given is an "apparent" value (i.e., with respect to an apparent source activity) and takes into account the attenuation of gamma rays within the implant capsule itself.

[6] Not applicable (NA) because the release activity is not based on beta emissions.

Supplement B

Procedures for Calculating Doses Based on Patient-Specific Factors

A licensee may release a patient to whom an activity with a value higher than the values listed in Column 1 of Table U.1 of this supplement has been administered if dose calculations using patient-specific parameters, which are less conservative than the conservative assumptions, show that the potential total effective dose equivalent to any individual would be no greater than 5 millisieverts (0.5 rem).

If the release of a patient is based on a patient-specific calculation that considered retained activity, an occupancy factor less than 0.25 at 1 meter, biological or effective half-life, or shielding by tissue, a record of the basis of the release is required by 10 CFR 35.75(c). The following equation can be used to calculate doses:

Equation B-1:
$$D(t) = \frac{34.6\ \Gamma\ Q_0\ TE\ (1 - e^{-0.693t/T_P})}{r^2}$$

Where:

	D(t)	=	Accumulated dose to time t, in rems
	34.6	=	Conversion factor of 24 hrs/day times the total integration of decay (1.44)
	Γ	=	Exposure rate constant for a point source, R/mCi x hr at 1 cm
	Q_0	=	Initial activity at the start of the time interval
	T_p	=	Physical half-life, in days
	E	=	Occupancy factor that accounts for different occupancy times and distances when an individual is around a patient
	r	=	Distance in centimeters. This value is typically 100 cm
	t	=	exposure time in days.

B.1 Occupancy Factor

B.1.1 Rationale for Occupancy Factors Used to Derive Table U.1

In Table U.1 in this appendix, the activities at which patients could be released were calculated using the physical half-life of the radionuclide and an occupancy factor at 1 meter of either 0.25 (if the radionuclide has a half-life longer than 1 day) or 1.0 (if the radionuclide has a half-life less than or equal to 1 day). The basis for the occupancy factor of 0.25 at 1 meter is that

measurements of doses to family members, as well as considerations of normal human behavior (as discussed in the supporting regulatory analysis (Ref. B-1)), suggest that an occupancy factor of 0.25 at 1 meter, when used in combination with the physical half-life, will produce a generally conservative estimate of the dose to family members when instructions on minimizing doses to others are given.

An occupancy factor of 0.25 at 1 meter is not considered appropriate when the physical half-life is less than or equal to 1 day, and hence, the dose is delivered over a short time. Specifically, the assumptions regarding patient behavior that led to an occupancy factor of 0.25 at 1 meter include the assumption that the patient will not be in close proximity to other individuals for several days; however, when the dose is from a short-lived radionuclide, the time that individuals spend in close proximity to the patient immediately following release will be most significant because the dose to other individuals could be a large fraction of the total dose from the short-lived radionuclide. Thus, to be conservative when providing generally applicable release quantities that may be used with little consideration of the specific details of a particular patient's release, the values calculated in Table U.1 were based on an occupancy factor of 1 at 1 meter when the half-life is less than or equal to 1 day.

B.1.2 Occupancy Factors to Consider for Patient-Specific Calculations

The selection of an occupancy factor for patient-specific calculations will depend on whether the physical or effective half-life of the radionuclide is used and whether instructions are provided to the patient before release. The following occupancy factors, *E*, at 1 meter, may be used for patient-specific calculations:

- E = 0.75 when a physical half-life, an effective half-life, or a specific time period under consideration (e.g., bladder holding time) is less than or equal to 1 day.
- E = 0.25 when an effective half-life is greater than 1 day, if the patient has been given instructions, such as:
  - — Maintain a prudent distance from others for at least the first 2 days;
  - — Sleep alone in a room for at least the first night;
  - — Do not travel by airplane or mass transportation for at least the first day;
  - — Do not travel on a prolonged automobile trip with others for at least the first 2 days;
  - — Have sole use of a bathroom for at least the first 2 days;
  - — Drink plenty of fluids for at least the first 2 days.

- E = 0.125 when an effective half-life is greater than 1 day if the patient has been given instructions, such as:
  - — Follow the instructions for E = 0.25 above;
  - — Live alone for at least the first 2 days;
  - — Have few visits by family or friends for at least the first 2 days.
- In a two-component model (e.g., uptake of iodine-131 using thyroidal and extrathyroidal components), if the effective half-life associated with one component is less than or equal to one day but is greater than one day for the other component, it is more justifiable to use the occupancy factor associated with the dominant component for both components.

Example 1: Calculate the maximum likely dose to an individual exposed to a patient who has received 2,220 megabecquerels (60 millicuries) of iodine-131. The patient received instructions to maintain a prudent distance from others for at least 2 days, lives alone, drives home alone, and stays at home for several days without visitors.

Solution: The dose to total decay (t = ∞) is calculated based on the physical half-life using Equation B-1. (This calculation illustrates the use of physical half-life. To account for biological elimination, calculations described in the next section should be used.)

$$D(\infty) = \frac{34.6\Gamma\, Q_0\, T_P\, E}{r^2}$$

Because the patient has received instructions for reducing exposure as recommended for an occupancy factor of E = 0.125, the occupancy factor of 0.125 at 1 meter may be used.

$$D(\infty) = \frac{34.6\ (2.2\ R\cdot\ cm^2/mCi\cdot hr)(60 mCi)(8.04\ d)(0.125)}{(100\ cm)^2}$$

D (∞) = 4.59 millisieverts (0.459 rem)

Since the dose is less than 5 millisieverts (0.5 rem), the patient may be released, but 10 CFR 35.75(b) requires that instructions be given to the patient on maintaining doses to others as low as is reasonably achievable. A record of the calculation must be maintained, pursuant to 10 CFR 35.75(c), because an occupancy factor of less than 0.25 at 1 meter was used.

B.2 Effective Half-Life

A licensee may take into account the effective half-life of the radioactive material to demonstrate compliance with the dose limits for individuals exposed to the patient that are stated in 10 CFR 35.75. The effective half-life is defined as:

Equation B-2: $$T_{eff} = \frac{T_b \ X \ T_p}{T_b \ + \ T_p}$$

Where: T_b = biological half-life of the radionuclide

T_p = physical half-life of the radionuclide.

The behavior of iodine-131 can be modeled using two components: extrathyroidal iodide (i.e., existing outside of the thyroid) and thyroidal iodide following uptake by the thyroid. The effective half-lives for the extrathyroidal and thyroidal fractions (i.e., F_1 and F_2, respectively) can be calculated with the following equations.

Equation B-3: $$T_{1eff} = \frac{T_{b1} \ X \ T_P}{T_{b1} \ + \ T_P}$$

Equation B-4: $$T_{2eff} = \frac{T_{b2} \ X \ T_P}{T_{b2} \ + \ T_P}$$

Where: T_{b1} = biological half-life for extrathyroidal iodide

T_{b2} = biological half-life of iodide following uptake by the thyroid

T_p = physical half-life of iodine-131.

However, simple exponential excretion models do not account for: (a) the time for the iodine-131 to be absorbed from the stomach to the blood; and (b) the holdup of iodine in the urine while in the bladder. Failure to account for these factors could result in an underestimate of the dose to another individual. Therefore, this supplement makes a conservative approximation to account for these factors by assuming that, during the first 8 hours after the administration, about 80% of the iodine administered is removed from the body at a rate determined only by the physical half-life of iodine-131.

Thus, an equation to calculate the dose from a patient administered iodine-131 may have three components. First is the dose for the first 8 hours (0.33 day) after administration. This component comes directly from Equation B-1, using the physical half-life and a factor of 80%. Second is the dose from the extrathyroidal component from 8 hours to total decay. In this component, the first exponential factor represents the activity at t = 8 hours based on the physical half-life of iodine-131. The second exponential factor represents the activity from t = 8 hours to total decay based on the effective half-life of the extrathyroidal component. The third component, the dose from the thyroidal component for 8 hours to total decay, is calculated in the same manner as the second component. The full equation is shown as Equation B-5.

Equation B-5:
$$D(\infty) = \frac{34.6\Gamma\ Q_0}{(100cm)^2}\{E_1\ T_P\ (0.8)(1-e^{-0.693(0.33)/Tp})$$

$$+ e^{-0.693(0.33)/Tp}\ E_2\ F_1\ T_{1eff} + e^{-0.693(0.33)/Tp}\ E_2\ F_2\ T_{2eff}$$

Where:
- F_1 = Extrathyroidal uptake fraction
- F_2 = Thyroidal uptake fraction
- E_1 = Occupancy factor for the first 8 hours
- E_2 = Occupancy factor from 8 hours to total decay.

All the other parameters are as defined in Equations B-1, B-3, and B-4. Acceptable values for F_1, $T_{1\,eff}$, F_2, and T_{2eff} are shown in Table U.6 for thyroid ablation and treatment of thyroid remnants after surgical removal of the thyroid for thyroid cancer. If these values have been measured for a specific individual, the measured values may be used.

The record of the patient's release required by 10 CFR 35.75(c) is described in Item U.3.1 of this appendix.

Example 2, Thyroid Cancer: Calculate the maximum likely dose to an individual exposed to a patient to whom 5550 megabecquerels (150 millicuries) of iodine-131 have been administered for the treatment of thyroid remnants and metastases.

Solution: In this example, we will calculate the dose by using Equation B-5 to account for the elimination of iodine-131 from the body, based on the effective half-lives appropriate for thyroid cancer. The physical half-life and the exposure rate constant are from Table U.5. The uptake fractions and effective half-lives are from Table U.6. An occupancy factor, *E*, of 0.75 at 1 meter, will be used for the first component because the time period under consideration is less than 1 day; however, for the second and third components, an occupancy factor of 0.25 will be used,

because: (1) the effective half-life associated with the dominant component is greater than 1 day; and (2) patient-specific questions were provided to the patient to justify the occupancy factor (see Section B.1.2, "Occupancy Factors to Consider for patient-Specific Calculations," of this Supplement).

Table U.6 Uptake Fractions and Effective Half-Lives for Iodine-131 Treatments.

Medical Condition	Extrathyroidal Component		Thyroidal Component	
	Uptake Fraction F_1	Effective Half-Life T_{1eff} (day)	Uptake Fraction F_2	Effective Half-Life T_{2eff} (day)
Hyperthyroidism	0.20[1]	0.32[2]	0.80[1]	5.2[1]
Post Thyroidectomy for Thyroid Cancer	0.95[3]	0.32[2]	0.05[3]	7.3[2]

[1] M.G. Stabin et al., "Radiation Dosimetry for the Adult Female and Fetus from Iodine-131 Administration in Hyperthyroidism," *Journal of Nuclear Medicine*, Volume 32, Number 5, May 1991. The thyroid uptake fraction of 0.80 was selected as one that is seldom exceeded by the data shown in Figure 1 in this referenced document. The effective half-life of 5.2 days for the thyroidal component was derived from a biological half-life of 15 days, which was obtained from a straight-line fit that accounts for about 75% of the data points shown in Figure 1 of the *Journal of Nuclear Medicine* document.

[2] International Commission on Radiological Protection (ICRP), "Radiation Dose to Patients from Radiopharmaceuticals," ICRP Publication No. 53, March 1987. (Available for sale from Pergamon Press, Inc., Elmsford, NY 10523.) The data in that document suggest that the extrathyroidal component effective half-life in normal subjects is about 0.32 days. Lacking other data, this value is applied to hyperthyroid and thyroid cancer patients. For thyroid cancer, the thyroidal component effective half-life of 7.3 days is based on a biological half-life of 80 days (adult thyroid), as suggested in the ICRP document.

[3] The thyroidal uptake fraction of 0.05 was recommended by Dr. M. Pollycove, M.D., NRC medical visiting fellow, as an upper-limit post-thyroidectomy for thyroid cancer.

Substituting the appropriate values into Equation B-5, the dose to total decay is:

$$D(\infty) = \frac{34.6\ (2.2)\ (150)}{(100cm)^2}\{(0.75)\ (8.04)\ (0.8)(1-e^{-0.693(0.33)/8.04})$$

$$+ e^{-0.693(0.33)/8.04}\ (0.25)(0.95)(0.32) + e^{-0.693(0.33)/8.04}\ (0.25)(0.05)(7.3)\}$$

$$D(\infty) = 3.40 \text{ millisieverts } (0.340 \text{ rem})$$

Therefore, thyroid cancer patients to whom 5550 megabecquerels (150 millicuries) of iodine-131 or less has been administered would not have to remain under licensee control and could be released under 10 CFR 35.75, assuming that the foregoing assumptions can be justified for the individual patient's case and that the patient is given instructions. Patients administered somewhat larger activities could also be released immediately if the dose is not greater than 5 millisieverts (0.5 rem).

In the example above, the thyroidal fraction, $F_2 = 0.05$, is a conservative assumption for persons who have had surgery to remove thyroidal tissue. If F_2 has been measured for a specific patient, the measured value may be used.

Example 3, Hyperthyroidism: Calculate the maximum likely dose to an individual exposed to a patient to whom 2035 megabecquerels (55 millicuries) of iodine-131 has been administered for the treatment of hyperthyroidism (i.e., thyroid ablation).

Solution: In this example, we will again calculate the dose using Equation B-5, Table U.5, and Table U.6, to account for the elimination of iodine-131 from the body by using the effective half-lives appropriate for hyperthyroidism. An occupancy factor, *E*, of 0.25 at 1 meter will be used for the second and third components of the equation because patient-specific instructions were provided to justify the occupancy factor (see Section B.1.2, "Occupancy Factors to Consider for Patient-Specific Calculations").

Substituting the appropriate values into Equation B-5, the dose to total decay is:

$$D(\infty) = \frac{34.6\ (2.2)\ (55)}{(100cm)^2}\{(0.75)\ (8.04)\ (0.8)(1-e^{-0.693(0.33)/8.04})$$

$$+ e^{-0.693(0.33)/8.04}\ (0.25)(0.20)(0.32) + e^{-0.693(0.33)/8.04}\ (0.25)(0.80)(5.2)\}$$

$$D(\infty) = 4.86 \text{ mSv } (0.486 \text{ rem})$$

Therefore, hyperthyroid patients to whom 2035 megabecquerels (55 millicuries) of iodine-131 has been administered would not have to remain under licensee control and could be released under 10 CFR 35.75 when the occupancy factor of 0.25 in the second and third components of the equation is justified.

In the example above, the thyroidal fraction $F_2 = 0.8$ is a conservative assumption for persons who have this treatment for hyperthyroidism. If F_2 has been measured for a specific patient, the measured value may be used.

B.3 Internal Dose

For some radionuclides, such as iodine-131, there may be concerns that the internal dose of an individual from exposure to a released patient could be significant. A rough estimate of the maximum likely committed effective dose equivalent from internal exposure can be calculated from Equation B-6.

Equation B-6: $D_i = Q\ (10^{-5})(DCF)$

Where:
- D_i = Maximum likely internal committed effective dose equivalent to the individual exposed to the patient in rems
- Q = Activity administered to the patient in millicuries
- 10^{-5} = Assumed fractional intake
- DCF = Dose conversion factor to convert an intake in millicuries to an internal committed effective dose equivalent (such as tabulated in Reference B-2).

Equation B-6 uses a value of 10^{-5} as the fraction of the activity administered to the patient that would be taken in by the individual exposed to the patient. A common rule of thumb is to assume that no more than 1 millionth of the activity being handled will become an intake to an

individual working with the material. This rule of thumb was developed in reference B-3 for cases of worker intakes during normal workplace operations, worker intakes from accidental exposures, and public intakes from accidental airborne releases from a facility, but it does not specifically apply to cases of intake by an individual exposed to a patient. However, two studies (Refs. B-4 and B-5) regarding the intakes of individuals exposed to patients administered iodine-131, indicated that intakes were generally of the order of 1 millionth of the activity administered to the patient and that internal doses were far below external doses. To account for the most highly exposed individual and to add a degree of conservatism to the calculations, a fractional transfer of 10^{-5} has been assumed.

Example 4, Internal Dose: Using the ingestion pathway, calculate the maximum internal dose to a person exposed to a patient to whom 1221 megabecquerels (33 millicuries) of iodine-131 has been administered. The ingestion pathway was selected because it is likely that most of the intake would be through the mouth or through the skin, which is most closely approximated by the ingestion pathway.

Solution: This is an example of the use of Equation B-6. The dose conversion factor DCF for the ingestion pathway is 53 rems/millicurie from Table 2.2 of Reference B-2.

Substituting the appropriate values into Equation B-6, the maximum internal dose to the person is:

$$D_i = (33 \text{ mCi})(10^{-5})(53 \text{ rem/mCi})$$

$$D_i = 0.17 \text{ mSv } (0.017 \text{ rem})$$

In this case, the external dose to the other person would be no greater than 5 millisieverts (0.5 rem), while the internal dose would-be about 0.17 millisievert (0.017 rem). Thus, the internal dose is about 3% of the external gamma dose. Internal doses may be ignored in the calculations if they are likely to be less than 10% of the external dose, because the internal dose would be significantly less than the uncertainty in the external dose.

The conclusion that internal contamination is relatively unimportant in the case of patient release was also reached by the NCRP. The NCRP addressed the risk of intake of radionuclides from patients' secretions and excreta in NCRP Commentary No. 11, "Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients" (Ref. B-6). The NCRP concluded, "Thus, a contamination incident that could lead to a significant intake of radioactive material is very unlikely." For additional discussion on the subject, see Reference B-1.

Example 5, Internal Dose: Calculate the maximum internal dose to a person exposed to a patient to whom 5550 megabecquerels (150 millicuries) of iodine-131 has been administered for the treatment of thyroid remnants and metastases.

Solution: In this example, we will again calculate the dose using Equation B-6 and selecting the ingestion pathway. Substituting the appropriate values into Equation B-6, the maximum internal dose to the person is:

$$D_i = (150 \text{ mCi})(10^{-5})(53 \text{ rem/mCi})$$

$$D_i = 0.80 \text{ mSv } (0.08 \text{ rem})$$

In this case, the external dose to the other person from Example 2, Thyroid Cancer, was approximately 3.4 millisieverts (0.34 rem), while the internal dose would be about 0.80 millisieverts (0.08 rem). Thus, the internal dose is about 24% of the external gamma dose. Therefore, the internal and external doses must be summed to determine the total dose; 4.2 millisieverts (0.42 rem).

References for Supplement B

B-1. S. Schneider and S.A. McGuire, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," USNRC, NUREG-1492, February 1997.

B-2. K.F. Eckerman, A.B. Wolbarst, and A.C.B. Richardson, "Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion," Federal Guidance Report No.11, U. S. Environmental Protection Agency, Washington, DC, 1988.

B-3. A. Brodsky, "Resuspension Factors and Probabilities of Intake of Material in Process (or 'Is 10^{-6} a Magic Number in Health Physics?')," *Health Physics*, Volume 39, Number 6, 1980.

B-4. R.C.T. Buchanan and J.M. Brindle, "Radioiodine Therapy to Out-patients – The Contamination Hazard," *British Journal of Radiology*, Volume 43, 1970.

B-5. A.P. Jacobson, P.A. Plato, and D. Toeroek, "Contamination of the Home Environment by Patients Treated with Iodine-131," *American Journal of Public Health*, Volume 68, Number 3, 1978.

B-6. National Council on Radiation Protection and Measurements, "Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients," Commentary No. 11, February 28, 1995.

Regulatory Analysis

"Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material" (NUREG-1492, February 1997) provides the regulatory basis and examines the costs and benefits. A copy of NUREG-1492 is available for inspection and copying for a fee at the NRC Public Document Room, 2120 L Street NW, Washington, DC. Copies may be purchased at current rates from the U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328 (telephone (202)512-2249), or from the National Technical Information Service by writing NTIS at 5285 Port Royal Road, Springfield, VA 22161.

Appendix V

Guidance for Mobile Services

Guidance for Mobile Services

Mobile service providers must comply with all applicable sections of 10 CFR Part 35. For example, mobile service providers offering remote afterloaders must comply with Subpart H of 10 CFR Part 35. In addition, under 10 CFR 30.34(e) mobile service providers are requested to provide detailed information about safe use of licensed material, storage of licensed material, and facilities and equipment, including the location of facilities, to ensure that the requirements in 10 CFR Part 20 and 10 CFR Part 35 are met.

Type and Location of Use

You should describe the type of mobile medical service to be provided. In general, there are three types of mobile service. One type is transportation and use of byproduct material within a transport vehicle (e.g., in-van use). A second type is transportation of byproduct material to a client's facility and use within a client's facility by the mobile service's employees (i.e., transport and use). A third type is transportation of byproduct material to a client's facility and use of the byproduct material by the client's employees (i.e., transport only). The third type of mobile service is limited to therapy sealed sources in devices that are transported to a client's facility.

For the first and second types, which include use by the service provider, the service provider must apply for full service authorization. For the third type, which is limited to transportation and storage of the therapy device, the service provider need only apply for authorization for possession and transport of the byproduct material. In this case, when the service provider is only transporting the therapy device for use, the client must possess a license for medical use of the byproduct material. Additionally, in this case, the client is authorized to provide the patient treatments and is responsible for all aspects of the byproduct material use and patient treatments upon transfer of the byproduct material to their possession.

For all types, licensed activities must be conducted in accordance with the regulations for compliance with 10 CFR 35.80(a), which states that you will obtain a letter signed by the management (i.e., chief executive officer or delegate) of each of your clients for which services are rendered. The letter will permit the use of byproduct material at the client's address and will clearly delineate the authority and responsibility of each entity. This agreement must be applicable for the entire period of time over which the service is to be provided. The letter will be retained for 3 years after the last provision of service, as required by 10 CFR 35.80(c) and 10 CFR 35.2080. Additionally, as required by 10 CFR 35.80(a)(4), you will survey to ensure compliance with the requirements in 10 CFR Part 20 (e.g., ensure that all byproduct material, including radiopharmaceuticals, sealed sources, and all associated wastes have been removed) before leaving a client's address.

The location of use for mobile medical services are of two basic types. One type of location is the base location where licensed material is received, stored, and sometimes used. The other type of location is the temporary job site at client facilities. The following two sections describe the type of information necessary for base locations and temporary job sites.

Base Location

The base location (e.g., central radiopharmaceutical laboratory or storage location for the remote afterloader) for the mobile service must be specified. The base facility may be located in a medical institution, non-institutional medical practice, commercial facility, or mobile van. You should specify in what type of facility the proposed base facility is located. A mobile licensee cannot provide a service to a private practice (non-licensee) located within a licensed medical institution (e.g., hospital). As required by 10 CFR 30.33 and 10 CFR 35.12, you must submit a detailed description and diagram(s) of the proposed base facility and associated equipment in accordance with Items 8.16 through 8.20 of this report. The description and diagram of the proposed facility must demonstrate that the building (or van) is of adequate construction and design to protect its contents from the elements (e.g., high winds, rain), ensures security of licensed material to prevent unauthorized access (e.g., control of keys), and ensures that radiation levels in unrestricted areas are in compliance with 10 CFR 20.1301. Include a diagram showing the location of the licensed material, receipt, and use areas, and identify all areas adjacent to restricted areas, including areas above and below the restricted areas. For storage locations within a van, the description of the van must address radiation levels in the van driver's compartment to demonstrate compliance with 10 CFR 20.1201, "Occupational dose limits for adults."

- You may request multiple base locations. Radioactive material must be delivered only to a facility licensed to receive the type of radioactive material ordered.
- Base locations can include the use of a mobile van. When the base facility is in the van, and there is no permanent structure for the byproduct material storage, you will have provisions for the following:
  - — Secured off-street parking under licensee control. Public rights-of-way are not considered part of the address of the client;
  - — Secured storage facilities available for storage of byproduct material and radioactive waste if the van is disabled; and
  - — Byproduct material delivered (if necessary) directly to the van only if the van is occupied by licensee personnel at the time of delivery.

- If a base facility is located in a residential area, you will provide the following information:
  - — Justification of the need for a private residence location rather than for a commercial location.
  - — Documentation of the agreement between the residence owner and the licensee. It is essential that the mobile service have access to the facility in the event of contamination. Provisions for decontamination of the mobile service van, etc., on the client property (if necessary) will be included. Documentation from both parties will illustrate the agreement between the client and the mobile service.
  - — A description of the program demonstrating compliance with 10 CFR 20.1301, "Dose limits for individual members of the public."
  - — Verification that restricted areas do not contain residential quarters.

Client Site

This section applies only to therapeutic uses of byproduct material. For all types of therapy uses, the medical institutions, hospitals, or clinics and their addresses that comprise the client sites for mobile services must be listed.

For self-contained byproduct material services (e.g., in-van) you must provide the following additional facility information:

- For therapy treatments with byproduct material (e.g., high dose-rate remote afterloader), a separate drawing for each client site showing the location of the treatment device/vehicle in relation to all nearby roads, sidewalks, structures, and any other locations accessible by members of the public;
- A signed agreement, as delineated in the letter required by 10 CFR 35.80(a), that location of the device/vehicle will be on client-owned or controlled property;
- The protection from vehicular traffic that could adversely affect patient treatment(s), that could be accomplished either by locating the facility away from all vehicular traffic or by using barriers. Any protective measures must be shown on the facility/site drawings provided.
- A description of the emergency lighting system that automatically activates on detection of the loss of primary power during patient remote afterloader treatments. The system must provide sufficient light to perform any possible emergency procedures, including the removal of a detached or stuck source that remains within the patient.

If you will provide transportable services to the client's site for use within the client's facility by the mobile service's employees, you must provide the following client facility information and commitment:

- A detailed description and diagram(s) of the proposed use facility (e.g., client site) and associated equipment in accordance with Items 8.16 through 8.20 of this report. The description and diagram of the proposed use facility must demonstrate that the facility is of adequate construction and design to protect its contents from the elements (e.g., high winds, rain), ensure security of licensed material to prevent unauthorized access, and ensure that radiation levels in unrestricted areas are in compliance with 10 CFR 20.1301. You must include a diagram showing the location of the equipment, receipt, and use areas, and identify all areas adjacent to restricted areas.
- A commitment, as delineated in the letter required by 10 CFR 35.80(a), that the mobile service licensee has full control of the treatment room during byproduct material use for each client.
- The initial installation records and function checks of a remote afterloader device for each site of use, as required by 10 CFR 35.633, 10 CFR 35.643, and 10 CFR 35.647.

For a transport-only mobile service for therapy devices that are transported to the client's facility, used by the client's staff (under their own license), and removed by the service provider, you must ensure the following:

- Each client is properly licensed for medical use of byproduct material. If applicable, you must ensure that each client has received the necessary initial and, if appropriate, recurrent training for the specific make and model of the remote afterloader device being provided. If the above applicable conditions are not met, the mobile service licensee must not transfer the remote afterloader device to the client.
- No signed agreement with a client may state or imply any assumption of responsibility on the part of the mobile service for the use of byproduct material for patient treatments. This includes such activities as dosage measurements, source calibrations, and remote afterloader device operational checks. Although these and other services may be provided to the client by the mobile service if the mobile service is specifically licensed to provide such services, the client (licensee) retains all of the responsibilities related to the use of the byproduct material for patient treatments. The responsibilities for supervising individuals who use the byproduct material, set forth in 10 CFR 35.27, transfer to the client's AUs upon transfer of the device to the client by the mobile service provider.
- The initial installation of a remote afterloader device at the client site may be performed by either the mobile service provider or the client, but all device function checks are the responsibility of the client (i.e., the licensee authorized to provide patient treatments at the client site).
- As required by 10 CFR 30.51, a formal record of the transfer of control of the byproduct material from the mobile service provider to the client, and from the client back to the mobile service provider, must be made for each transfer of byproduct material. A signed receipt of each transfer must be made and retained for inspection for 3 years.

Supervision

In addition to the requirements in 10 CFR 19.12, you will instruct supervised individuals in your written radiation protection procedures, written directive procedures, regulations, and license conditions with respect to the use of byproduct material. Additionally, you will require the supervised individual to:

- Follow the instructions of the supervising authorized user for medical uses of byproduct material;
- Follow the instructions of the supervising authorized nuclear pharmacists or supervising authorized user for preparation of byproduct material for medical uses;
- Follow the written radiation protection procedures and written directive procedures established by the licensee; and
- Comply with the provisions of 10 CFR Part 35, [e.g., 10 CFR 35.80 and 10 CFR 35.647 (if applicable)], and the license conditions with respect to the mobile medical use of byproduct material.

Training for Individuals Working in or Frequenting Restricted Areas

Drivers and technologists (or therapists) will be properly trained in applicable transportation regulations and emergency procedures in addition to the training requirements of 10 CFR 19.12, 10 CFR 35.27, 10 CFR 35.310, 10 CFR 35.410, and 10 CFR 35.610 (as applicable). The training for these individuals will include, at a minimum, DOT regulations (see Section 8.43 and Appendix W), shielding, ALARA, and basic radiation protection.

Survey Instrument and Dose Measurement Instrument Checks

As required by 10 CFR 35.80, you will check survey instruments for proper operation with a dedicated check source before use at each address of use. You will check dose measurement instruments (e.g., dose calibrators), as described in 10 CFR 35.60, before medical use at each address of use or on each day of use, whichever is more frequent. Additionally, all other transported equipment (e.g., cameras) should be checked for proper function before medical use at each address of use.

Order and Receipt of Byproduct Material

Byproduct material will be delivered by a supplier to the base location or to the client's address if the client is licensed to receive the type of byproduct material ordered. Delivery of byproduct material to a van that is not occupied by the mobile service personnel will not be permitted.

Alternatively, you may pick up the byproduct material (e.g., radiopharmaceuticals) from the supplier (e.g., nuclear pharmacy) en route to client facilities.

Emergency Procedures

You will develop, implement, and maintain emergency procedures, in accordance with your radiation protection program required by 10 CFR 20.1101 that, in part, will provide that the RSO, AU, or a responsible designee, will be physically present at the client's address in response to incidents (e.g., accidents, spills, medical events) that occur at client facilities. You will indicate typical response times of the RSO and AU in the event of an incident and develop and implement procedures that include emergency response regarding an accident scenario. An accident is defined as a vehicle collision or other event, such as, wind, water, or fire that results in damage to exterior or interior portions of the vehicle or the byproduct material used in the mobile service. The transportation emergency response plan will cover both the actions to be taken by the mobile service provider's headquarters emergency response personnel and the "on-scene" hazardous material-trained personnel, and it will be readily available to both transport vehicle personnel and headquarters emergency-response contacts. At a minimum, this plan will include the following:

- A 24-hour emergency contact telephone number for the mobile service provider's emergency response personnel;
- The emergency contact numbers for NRC's Operation Center and all appropriate state radiological protection agencies;
- Procedures for restricting access to the transport vehicle until surveys have been made to determine if any radiological hazards exist;
- Procedures for retrieving and securing any byproduct material, including a sealed source that may become detached and/or dislodged to the extent that a radiological hazard is created, which may require one or more emergency shielded source containers;
- Predetermined (calculated) exposure rates for an unshielded therapy source (if applicable) as a function of distance for use in controlling the exposures of emergency response personnel to the maximum extent possible under various emergency response scenarios;
- Preplanned decontamination procedures, including ready access to all necessary materials;
- A calibrated, operational survey meter maintained in the cab of the transporting vehicle, which may be used at an accident scene for conducting surveys;
- Security of the transport vehicle against unauthorized access, including the driver's compartment;
- Procedures to ensure that following any accident, no patient treatments with remote afterloaders will occur until all systems pertaining to radiation safety have been tested and

confirmed to be operational by the RSO or AMP. If any problem is found, including remote afterloader device interlocks and operation, the remote afterloader device or facility will be repaired and re-certified by the device vendor prior to return to service. In addition, a copy of the report, generated in accordance with 10 CFR 30.50, will be provided to clients following any accident in which there is actual or possible damage to the client's facility or the device.

Note: The type of response should be consistent with the level of the incident. The response may range from phone contact for minor spills to prompt on-site response (less than 3 hours) to events such as a medical event or lost radioactive material.

Transportation

You will develop, document, and implement procedures to assure that the following takes place:

- Radioactive material is transported in accordance with 49 CFR Parts 170–189. Procedures will include:
  - — Use of approved packages;
  - — Use of approved labeling;
  - — Conduct of proper surveys;
  - — Complete and accurate shipping papers;
  - — Bracing of packages;
  - — Security provisions;
  - — Written emergency instructions.
- Management (or management's designee) will perform audits, at least annually, of transportation documentation (e.g., shipping papers and survey reports) and activities at client facilities.
- Licensed material is secured during transport and use at the client's facilities.
- Radioactive waste is handled properly during transport. You will describe the method of storage and final disposal.
- The transport vehicle, including the driver's compartment, if separate, will be secured at all times from any unauthorized access when the vehicle is unattended.

Note: The necessary DOT Type 7A package certification for remote afterloader devices is established by prior approval of the appropriate sealed source and device sheets; however, if the remote afterloader device is damaged in any way during use or transport, then the integrity of the DOT Type 7A packaging may be compromised, and the device must not be used or transported until checked by the vendor and certified as retaining its integrity as a Type 7A package.

Radioactive Waste Management

If waste will be stored in vans, the vans will be properly secured and posted as byproduct material storage locations. You will ensure that the van will be secured against unauthorized access and that the waste storage location will be posted as a byproduct material storage area.

You will develop, document, and implement final waste disposal procedures in accordance with Section 8.44 of this report.

Excreta from individuals undergoing medical diagnosis or therapy with radioactive material may be disposed of without regard to radioactivity if it is discharged into the sanitary sewerage system, in accordance with 10 CFR 20.2003. However, collecting excreta from patients in a van restroom with a holding tank is not considered direct disposal into the sanitary sewerage system. If you will provide restroom facilities in the van for patient use, you must submit the following information for NRC review:

- A description of the structure of the tank holding facility and the location of the tank in relation to members of the public, workers in the van, and the driver of the van; a description of procedures to assess the tank for possible leakage; and a description of any restroom ventilation if any I-131 will be held in the tank.
- A description of procedures to ensure doses to occupational workers and members of the public will not exceed the exposure limits in 10 CFR 20.1201 and 20.1301, that the external surfaces of the van do not exceed 2 mrem/hour, and that doses to members of the public and workers are maintained ALARA, including considerations of external dose rates in the restroom caused by the proximity of the holding tank to the toilet.
- A description of procedures for emptying and disposing of the contents of the holding tank, including the frequency of disposal, who empties the tank into the sanitary sewer system, and the location of disposal into the sanitary sewer, including precautions taken to minimize contamination in this process.

Mobile Services With Remote Afterloader Devices

In addition to the above procedures addressed in the mobile services section, you will develop, document, and implement the following procedures regarding mobile remote afterloader service operations:

- Because the movement of the remote afterloader device from one location to another increases the risk of electro-mechanical component failures or misalignments, it is important that the proper operation of the device be fully checked after each such relocation. Therefore, you will develop, document, and implement the following procedures to determine if a device is operating properly before the commencement of patient treatments:

- Safety checks conducted on a remote afterloader device and facility. The procedure will, at a minimum, include the periodic spot checks required by 10 CFR 35.643 and the additional spot checks required by 10 CFR 35.647 before medical use following any relocation of the device. Additionally, the procedure must include provisions for prompt repair of any system not operating properly.
- The pretreatment operational function checks after each device move must include a review of any device alarm or error message and, if necessary, a resolution of problems indicated by such messages.
- Such tests, as indicated above, must be performed in accordance with written procedures established by the AMP identified on the license authorizing patient treatments.
- You must maintain records, as described in 10 CFR 35.2647 and 10 CFR 35.2643, showing the results of the above safety checks for NRC inspection and review for a period of 3 years.

- You will conduct radiation surveys before initiating the treatment program (baseline surveys). These baseline surveys must include the source housing, with the source in the shielded position and all areas adjacent to the treatment room with the source in the treatment position. Immediately following any relocation of the remote afterloader device, and before patient treatments, the licensee must conduct such surveys, as necessary, with a portable, calibrated survey meter, to ensure the radiation dose rates obtained are comparable to those obtained from the baseline surveys. Any significant increase in the dose rates found after relocation from the baseline survey results suggests that the shielding integrity may have been compromised and the problem must be investigated and resolved before the remote afterloader device is used.

Appendix W

Transportation

Transportation

Licensed material must be transported in accordance with DOT regulations. The major areas in the DOT regulations that are most relevant for transportation of Type A or Type B quantities of licensed material are:

- Table of Hazardous Materials and Special Provisions 49 CFR 172.101, and App. A, Table 2: Hazardous materials table, list of hazardous substances, and reportable quantities;
- Shipping Papers 49 CFR 172.200-204: General entries, description, additional description requirements, shipper's certification;
- Package Markings 49 CFR 172.300, 49 CFR 172.301, 49 CFR 172.303, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 172.324: General marking requirements for non-bulk packagings, prohibited marking, marking requirements, radioactive material, hazardous substances in non-bulk packaging;
- Package Labeling 49 CFR 172.400, 49 CFR 172.401, 49 CFR 172.403, 49 CFR 172.406, 49 CFR 172.407, 49 CFR 172.436, 49 CFR 172.438, 49 CFR 172.440: General labeling requirements, prohibited labeling, radioactive materials, placement of labels, specifications for radioactive labels;
- Placarding of Vehicles 49 CFR 172.500, 49 CFR 172.502, 49 CFR 172.504, 49 CFR 172.506, 49 CFR 172.516, 49 CFR 172.519, 49 CFR 172.556: Applicability, prohibited and permissive placarding, general placarding requirements, providing and affixing placards: highway, visibility and display of placards, RADIOACTIVE placard;
- Emergency Response Information, Subpart G, 49 CFR 172.600, 49 CFR 172.602, 49 CFR 172.604: Applicability and general requirements, emergency response information, emergency response telephone number;
- Training, Subpart H, 49 CFR 172.702, 49 CFR 172.704: Applicability and responsibility for training and testing, training requirements;
- Radiation Protection Program for Shippers and Carriers, Subpart I, 49 CFR 172.800, etc.;
- Shippers – General Requirements for Shipments and Packaging, Subpart I, 49 CFR 173.403, 49 CFR 173.410, 49 CFR 173.411, 49 CFR 173.412, 49 CFR 173.413, 49 CFR 173.415, 49 CFR 173.416, 49 CFR 173.433, 49 CFR 173.435, 49 CFR 173.441, 49 CFR 173.471, 49 CFR 173.475, 49 CFR 173.476: Definitions, general design requirements, industrial packages, additional design requirements for Type A packages, requirements for Type B packages, authorized Type A packages, authorized Type B packages (including package certification requirements), requirement for determining A1 and A2..., table of A1 and A2 values for radionuclides, radiation level limit, requirements for USNRC-approved packages (Type B), quality control requirements prior to each shipment..., approval of special form radioactive materials;

- Carriage by Public Highway 49 CFR 177.816, 49 CFR 177.817, 49 CFR 177.834(a), 49 CFR 177.842: Driver training, shipping paper, general requirements (secured against movement), Class 7 (radioactive) material.

For additional transportation information, licensees may consult DOT's "A Review of the Department of Transportation Regulations for Transportation of Radioactive Materials" or contact the DOT at http://www.dot.gov.

Appendix X

Model Procedure for Waste Disposal by Decay-In-Storage, Generator Return, and Licensed Material Return

Model Procedure for Waste Disposal by Decay-In-Storage, Generator Return, and Licensed Material Return

This model provides acceptable procedures for waste disposal. You may either adopt these model procedures or develop your own procedures to meet the requirements of Subpart K to 10 CFR Part 20, 10 CFR 20.1101, and 10 CFR 35.92.

Model Procedure for Decay-In-Storage

10 CFR 35.92 describes the requirements for DIS. Storage should be designed to allow for segregation of wastes with different half-lives (e.g., multiple shielded containers). Containers should have shielded covers to maintain occupational exposure at ALARA levels. Storage areas must be in a secure location.

- If possible, we will use separate containers for different types of waste, e.g., needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container. Because the waste will be surveyed with all shielding removed, the containers in which the waste will be disposed of must not provide any radiation shielding for the material.
- When the container is full, we will seal it and attach an identification tag that includes the date sealed and the longest-lived radionuclide in the container. The container may then be transferred to the DIS area.
- Prior to disposal as in-house waste, we will monitor and record the monitoring of each container as follows:
  - — Use a survey instrument that is appropriate for the type and energy of the radiation being measured;
  - — Check the radiation detection survey meter for proper operation and current calibration status;
  - — Monitor in a low-level radiation (<0.05 millirem per hour) area away from all sources of radioactive material, if possible;
  - — Remove any shielding from around the container or generator column;
  - — Monitor, at contact, all surfaces of each individual container;
  - — Remove or deface any radioactive material labels (unless the containers will be managed as biomedical waste after they have been released from the licensee as described in 10 CFR 35.92);
  - — Discard as in-house waste only those containers that cannot be distinguished from background. Containers may include trash bags full of waste, generator columns, and biohazard (needle) boxes. Record the disposal date, the radionuclides disposed, the survey

instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal;

— Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred to an authorized byproduct material recipient.

Model Procedure for Returning Generators to the Manufacturer

Used Mo/Tc-99m generators may be returned to the manufacturer. This permission does not relieve licensees from the requirement to comply with 10 CFR Part 71 and DOT regulations. We will perform the following actions when returning generators:

- Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container (see DOT regulations, paragraph 173.415 (a) of 49 CFR Part 173);
- Assemble the package in accordance with the manufacturer's instructions;
- Perform the dose rate and removable contamination measurements required by paragraph 173.475(i) of 49 CFR Part 173;
- Label the package and complete the shipping papers in accordance with the manufacturer's instructions;
- Retain records of receipts and transfers in accordance with 10 CFR 30.51.

Model Procedure for Return of Licensed Material to Authorized Recipients

We will perform the following steps when returning licensed material to authorized recipients:

- In accordance with 10 CFR 30.41(a)(5), confirm that persons are authorized to receive byproduct material prior to transfer (e.g., obtain a copy of the transferee's NRC license or Agreement State license that authorizes the byproduct material);
- Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container (see DOT regulations, paragraph 173.415 (a) of 49 CFR Part 173);
- Assemble the package in accordance with the manufacturer's instructions;
- Perform the dose rate and removable contamination measurements required by paragraph 173.475(i) of 49 CFR Part 173;
- Label the package and complete the shipping papers in accordance with the manufacturer's instructions;
- Retain records of receipts and transfers in accordance with 10 CFR 30.51.

Appendix Y

NRC Form 314

NRC FORM 314 (7-1998)
10 CFR 30.36(c)(1)(iv)
10 CFR 40.42(c)(1)(iv)
10 CFR 70.38(c)(1)(iv)

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0028 EXPIRES: 07/31/2001

Estimated burden per response to comply with this mandatory information collection request: 30 minutes. This submittal is used by NRC as part of the basis for its determination that the facility has been cleared of radioactive material before the facility is released for unrestricted use. Forward comments regarding burden estimate to the Records Management Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and to the Paperwork Reduction Project (3150-0028), Office of Management and Budget, Washington, DC 20503. If an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

CERTIFICATE OF DISPOSITION OF MATERIALS

INSTRUCTIONS: ALL ITEMS MUST BE COMPLETED -- PRINT OR TYPE
SEND THE COMPLETED CERTIFICATE TO THE NRC OFFICE SPECIFIED ON THE REVERSE

LICENSEE NAME AND ADDRESS	LICENSE NUMBER
	LICENSE EXPIRATION DATE

A. MATERIALS DATA *(Check one and complete as necessary)*

THE LICENSEE OR ANY INDIVIDUAL EXECUTING THIS CERTIFICATE ON BEHALF OF THE LICENSEE CERTIFIES THAT:
(Check and/or complete the appropriate item(s) below.)

☐ 1. NO MATERIALS HAVE EVER BEEN PROCURED OR POSSESSED BY THE LICENSEE UNDER THIS LICENSE.

OR

☐ 2. ALL ACTIVITIES AUTHORIZED BY THE LICENSE HAVE CEASED AND ALL MATERIALS PROCURED AND/OR POSSESSED BY THE LICENSEE UNDER THE LICENSE NUMBER CITED ABOVE HAVE BEEN DISPOSED OF IN THE FOLLOWING MANNER. *(If additional space is needed, use the reverse side or provide attachments.)*

Describe specific material transfer actions and, if there were radioactive wastes generated in terminating this license, the disposal actions including the disposition of low-level radioactive waste, mixed waste, Greater-than-Class-C waste, and sealed sources, if applicable.

For transfers, specify the date of the transfer, the name of the licensed recipient, and the recipient's NRC license number or Agreement State name and license number.

If materials were disposed of directly by the licensee rather than transferred to another licensee, licensed disposal site or waste contractor, describe the specific disposal procedures *(e.g., decay in storage)*.

B. OTHER DATA

☐ 1. OUR LICENSE HAS NOT YET EXPIRED; PLEASE TERMINATE IT.

2. A RADIATION SURVEY WAS CONDUCTED BY THE LICENSEE TO CONFIRM THE ABSENCE OF LICENSED RADIOACTIVE MATERIALS AND TO DETERMINE WHETHER ANY CONTAMINATION REMAINS ON THE PREMISES COVERED BY THE LICENSE.

☐ NO *(Attach explanation)*
☐ YES, THE RESULTS *(Check one)*
☐ ARE ATTACHED, or
☐ WERE FORWARDED TO NRC ON *(Date)*

3. THE PERSON TO BE CONTACTED REGARDING THE INFORMATION PROVIDED ON THIS FORM	NAME	TELEPHONE NUMBER *(Include Area Code)*

4. MAIL ALL FUTURE CORRESPONDENCE REGARDING THIS LICENSE TO

CERTIFYING OFFICIAL

I CERTIFY UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT

PRINTED NAME AND TITLE	SIGNATURE	DATE

WARNING: FALSE STATEMENTS IN THIS CERTIFICATE MAY BE SUBJECT TO CIVIL AND/OR CRIMINAL PENALTIES. NRC REGULATIONS REQUIRE THAT SUBMISSIONS TO THE NRC BE COMPLETE AND ACCURATE IN ALL MATERIAL RESPECTS. 18 U.S.C. SECTION 1001 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTIONS.

NRC FORM 314 (7-1998) PRINTED ON RECYCLED PAPER

FILE CERTIFICATES AS FOLLOWS:

IF YOU ARE A DISTRIBUTOR OF EXEMPT PRODUCTS, SEND TO:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHERS, IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANCE SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

NUCLEAR MATERIALS SAFETY SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
ATLANTA FEDERAL CENTER, SUITE 23T85
61 FORSYTH STREET, SW
ATLANTA, GA 30303-3415

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE ROAD
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

MATERIAL RADIATION PROTECTION SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

Appendix Z

Comments on Draft

Table Z.1 Comments Provided by the American College of Nuclear Physicians, California Chapter, Dated November 9 and December 2, 1998.

Location	Subject	Comment
Entire Document	Request that the Commission review the basis for the rule and guidance	At the public meeting on the Proposed Part 35 and NUREG-1556, Volume 9, a representative from SNM and ACNP put the following critical questions to the NRC Commissioners: • Apparent determination by the Commission that the Atomic Energy Act has misinterpreted for over 40 years and that in fact NRC has responsibility for controlling the practices of nuclear medicine and nuclear pharmacy in order to ensure "patient radiation safety." • NRC's newly found power apparently now extends to determining which radiopharmaceuticals are allowed to be given to patients, in what doses, and for what medical conditions, and extends as well to how the drugs are prepared. • NRC has now published in the *Federal Register* that it has the power to practice medicine and pharmacy in 50 states without a license and without seeing patients. • The Commission has determined that it cannot use concepts of relative risk in its risk assessment because it is forbidden to do so by the Atomic Energy Act. However, it is theoretically impossible to have a "risk informed" role in medicine if relative risk is not considered.
NRC Staff Response: The aforementioned comments appear to address the 10 CFR Part 35 Rule Text, which is not within the scope of this document. Additionally, NUREG-1556, Volume 9, makes no attempt to establish additional requirements for medical licensees.		
Entire Document	Document ignores recommendations of the Institute of Medicine	All of these documents (NUREG-1556 Volumes 9 and 11 and the proposed revision of 10 CFR Part 35) ignore and fail to implement the recommendations in the report from the Institute of Medicine (IOM) of the National Academy of Sciences.

Location	Subject	Comment
NRC Staff Response: The IOM recommendations concerned the regulation of the medical uses of byproduct, source, and special nuclear material. ACNP-CA's comment appears to apply to the proposed revision of 10 CFR Part 35 and not the guidance document, per se. NUREG-1556, Volume 9, is intended to provide guidance, not requirements, for medical licensees.		
Entire Document	Document is not risk related and performance based	The NRC promised that both the revised Part 35 and the NUREGs would be risk related and performance based. They are neither!
NRC Staff Response: We believe that NUREG-1556, Volume 9, is risk-related and performance-based. NRC recognizes the low risk associated with many licensed activities and the ability of medical licensees to develop safe procedures without direct NRC involvement. Because of this, the guidance in Volume 9 was designed to reduce the amount of detailed information that a licensee is required to submit to NRC for review during the licensing process. The adequacy of the licensee's procedures, implementation of the procedures, and the ability of the licensee through these procedures to meet specific performance indicators, will be evaluated during inspections.		
Entire Document	Document reveals an increase in regulations and other requirements and increased costs	The NRC also stated that regulatory activity and costs would be decreased, but a review of the proposed Part 35 and the two latest NUREGs (NUREG-1556, Volumes 9 and 11) reveals an increase in regulations and other requirements and increased costs.
NRC Staff Response: We do not believe that NUREG-1556, Volume 9, reveals an increase in regulations, requirements, or costs. Volume 9 does not create any regulations. Also, since the NUREG was designed to reduce the amount of information submitted during the amendment and/or licensing process, the cost to the licensee should be reduced.		
Entire Document	NRC limited areas of public comment	The NRC had promised to have an open and unbiased review of these documents, but they again violated their trust by limiting the areas of public comment only to the questions unilaterally framed by the NRC.
NRC Staff Response: Public comment on NUREG-1556, Volume 9, was requested, and desired, in all areas. There was no limiting of the areas for public comment.		

Location	Subject	Comment
Entire Document	Insufficient comment period established by NRC	We and other organizations had requested a one year delay in order to permit time for an honest discourse between the NRC and interested parties in order to resolve these many important problems. Instead, I was recently informed that the NRC has extended the comment period for only one month. This is apparently not a month for discussion of outstanding problems, but merely another month to comment on these flawed documents. Again, we urge a one-year delay for a reconsideration of Part 35, as well as NUREG-1556, Volume 9.
NRC Staff Response: This comment appears to apply only to the proposed revision of Part 35 and not to NUREG-1556, Volume 9. NRC accepted comments on the draft NUREG until finalized approximately 2 years later. We, therefore, believe that the period available for comment was sufficient.		
Entire Document	Development of procedures	The Proposed Part 35 package restricts qualified nuclear medicine physicians from freely choosing among drugs for various patient conditions by limited procedure by procedure licensing.
NRC Staff Response: The comment appears to address the 10 CFR Part 35 Rule Text, which is not within the scope of this document. NUREG-1556, Volume 9, makes no attempt to establish additional requirements for medical licensees. The license restriction to a type of medical use for a given authorized user reflects the amount of training achieved by the authorized user. 10 CFR Part 35 mandates the amount of training required for each type of medical use.		
Appendix L	Model Procedures for an Occupational Dose Program	NRC's thyroid bioassay requirements for Na I-131 are outdated and unnecessary. All commercial products are stabilized against volatility, and have been so for over 10 years. NRC has been sent the full scientific database at least three times showing extremely low volatility. Why cannot NRC understand and use these data? In California, thyroid bioassay is not required when using stabilized products.
NRC Staff Response: The detailed procedures were replaced with a referral to the appropriate Regulatory Guides and NUREG that cover this subject in greater detail.		

Location	Subject	Comment
Appendix R	Model Procedure for Area Surveys	Another example is limits, in dpm/100 cm^2 of removable contamination. First, the whole concept of numerical limits is flawed, and the old 2000 dpm/100 cm^2 for all radionuclides except I-131, which was 200, is already arbitrary and capricious. Only radiation absorbed dose matters. However, without a shred of scientific justification, NRC lowers the 2000 to 1000, keeps the 200 for I-131, and makes a limit of 20 dpm/100 cm^2 for I-125. Radiation absorbed dose from such levels of I-125 are absurdly minuscule. We do not even have equipment that can detect this. Background in a NaI (TI) system at the I-125 setting is commonly about 30 cpm, and in a typical liquid scintillation counter is about 35 cpm. Efficiency for a NaI (TI) bioassay system is about 1%.
NRC Staff Response: We agree that the suggested trigger level documented in Table R.3 of 20 dpm/100 cm^2 set for I-125 and I-129 appears low. This value and the other values in the table were chosen to be consistent with the values provided in guidance for release of facilities and equipment (Policy and Guidance Directive FC 83-23). However, consistent with the grouping used in Table R.2, I-125 was moved to be grouped with I-131. Additionally, transuranics and I-129 were deleted from this table, since medical licensees do not normally use transuranics or unsealed I-129.		

Location	Subject	Comment
Appendix X	Model Procedure for Waste Disposal by Decay-In-Storage, Generator Return, and Licensed Material Return	The requirement in Appendix X to remove the sharps from the sharps box to avoid any shielding is a massive OSHA violation. It could, for example, kill workers from hepatitis B or C, or AIDS.
NRC Staff Response: The model procedures provide acceptable procedures for waste disposal. Licensees may either adopt the model procedures or develop their own procedures to meet the requirements. However, the statement made in the NUREG is "because the waste will be surveyed with all shielding removed, the containers in which the waste will be disposed of must not provide any radiation shielding for the material." This would allow the sharps to remain within the sharps box, as long as the sharps box did not provide radiation shielding for the material. If this is not true, the licensee should consider another type of disposal container to use as a sharps box.		

Table Z.2 Comments Provided by the American College of Nuclear Physicians/Society of Nuclear Medicine, Dated December 16, 1998.

Location	Subject	Comment
Entire Document	Use of Professional Organizations to Develop Guidance	The NUREG includes numerous areas that cannot be understand or should not be included. Following are a few examples (among the many detected) of the problems with this NUREG and strongly recommend that NRC retract this document until such time that a workshop with stakeholders can be convened. The purpose of the workshop would be to go over the model procedures to determine which, if any, are necessary to maintain compliance with 10 CFR Part 20. Licensees, in order to make the licensing process as easy as possible, are likely to incorporate the model suggestions made by NRC. If these suggestions are incorrect, scientifically or medically flawed, then patient safety could be in jeopardy. The NRC should get out of providing model procedures as the benchmark for what they would accept. This only takes away the flexibility of licensees and leads them to accepting bad suggestions from the agency. If the licensee is incapable of operating a nuclear medicine department in compliance with the standards of 10 CFR part 20, without the NRC's model procedures, we suspect they are unqualified to be licensed. We reiterate that this NUREG should be retracted until such time that a workshop with stakeholders can be convened to go over the procedures to determine which, if any, are necessary to maintain compliance with part 20.
NRC Staff Response: NRC sought to develop the NUREG licensing guidance concurrently with the proposed regulation in an effort to better serve the regulated community. This method allowed the regulated community to comment on the proposed rule and the proposed licensing guidance simultaneously. Although there are drawbacks to this method, NRC believes that the benefits of this method outweigh the drawbacks. Additionally, we believe that NUREG-1556, Volume 9, is risk-related and performance-based. NRC recognizes the low risk associated with many licensed activities and the ability of medical licensees to develop safe procedures without direct NRC involvement. The model procedures were developed using multiple references, including documents issued by ANSI, ICRP, NCRP, and AAPM. Additionally, we have incorporated several clarifications to these procedures based on specific comments supplied by stakeholders. We believe that licensees will find these model procedures useful when developing their own procedures.		

Location	Subject	Comment
Appendix C	License Application Checklist and Sample Licenses	Page C-11: At bottom of page, in box #9, in sentences A, B, and C, the NUREG refers to "procedure approved in 10 CFR 35.100" or 35.200, or 35.300. First of all the regulations do not refer to "procedures," but to "studies." Secondly, there is no NRC regulatory mechanism to approve any patient study. Does this mean that only specific procedures that are approved by NRC will be acceptable? We recommend that there be no restriction on the use of byproduct material for medical purposes as long as the authorized user meets the Training and Experience requirements of §§ 35.100, 35.200, and 35.300.
NRC Staff Response: The language found in License Condition 9 reflects the type of medical use requested by the licensee. The condition also relies on the training and experience attained by the authorized users and limits the types of use (e.g., 35.100, 35.200, etc.) to those for which the licensee has appropriately trained authorized users. However, we agree that the word "study" is used in 10 CFR 35.100 and 10 CFR 35.200, not "procedure," and we have revised the license condition accordingly.		

Location	Subject	Comment
Appendix I	Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program	Pages I-3, 4, and 5: By our account, and that of certified health physics professionals asked for opinions, an incomplete formula for determination of counting efficiency is provided. Additionally, the instructions are incomplete, and if followed as written could lead to gross underestimation of removable contamination in certain situations. This situation leads to our concern about other areas that seem incomplete.
NRC Staff Response: The efficiency calculation referenced in the NUREG is the absolute efficiency. This efficiency is dependent on the counting geometry. A notation to this effect was added to the discussion. Additionally, the calculation was revised to clarify that the true counts of the calibration source applies to the 2π emission rate from the calibration source. However, applicants are not required to implement the model procedure and may instead elect to use the intrinsic efficiency, which no longer includes the solid angle subtended by the detector and has much less of a dependence on the counting geometry.		
Appendix N	Emergency Procedures	• Page N-3: The section entitled "Emergency Surgery of Patients Who Have Received Therapeutic Amounts of Radionuclides." Sentence #3 is the most obvious example of NRC's lack of knowledge of medical practice. Very few RSO's are properly trained to enter the operating room during a surgical procedure or are knowledgeable enough about surgery to tell a surgeon how to operate? • The title of this section is "Emergency Surgery." Based on our calculations, it is impossible for a surgeon or personnel to get enough radiation exposure from a patient during a procedure to warrant the statement. Surgeons have far more to worry about than some radiation exposure. They worry about infection and saving the patient's life. These flaws illustrate a pattern throughout the NUREG that places requirements that have not been reviewed into the regulations.
NRC Staff Response: • Item 3 under "Emergency Surgery of Patients Who Have Received Therapeutic Amounts of Radionuclides" does not discuss the presence of the RSO in the operating room. The item states that "the RSO will direct personnel in methods to keep doses ALARA during surgical procedures." Therefore, this item does not require RSO presence within the operating room. • The use of the phrase "emergency surgery" does not necessarily imply a radiation emergency. The emergency may be, for example, heart failure that results in open heart		

Table Z.3 Comments Provided by the Cleveland Clinic Foundation, Dated December 4, 1998.

Location	Subject	Comment
Section 8.31	Use Records	Change "Prescribed dosage and activity at the time of determination, or a notation that the total activity is less than 1.1 mega-Bq (30 μCi)" to "Prescribed dosage and activity at the time of determination (unless already recorded in a clinical procedure manual, or on a dosage list of routine clinical procedures) or a notation that the total activity is less than 1.1 mega-Bq (30 μCi)."
NRC Staff Response: This comment appears to apply only to the proposed revision of 10 CFR Part 35, i.e., 10 CFR 35.2063, and not the guidance document.		

Table Z.4 Comments Provided by the Kettering Medical Center, Dated September 15, November 11 and December 4, 1998.

Location	Subject	Comment
Appendix L	Occupational Dose-Investigational Levels	• The investigational levels used in monitoring external exposures as listed in Table L.1 Investigational Levels (NUREG-1556) should be changed. Those levels do not reflect the current limits as defined in 10 CFR Part 20. Only the whole body level is correct in terms of current regulations. The extremities limits listed are too high and the skin of whole body is too low. Also, the lens of the eye should be separately listed to correctly reflect the current regulations. • Historically, the Investigational Levels I and II were 10% and 30% of the allowable annual dose limits in the Model ALARA program (Reg. Guide 10.8, rev. 2) for most medical programs. When those occupational dose limits were changed in 1994 with the revision of 10 CFR Part 20, many medical programs changed the Investigational Levels I and II to reflect the new regulations. In providing annual radiation safety instructions, I find that radiation workers can better relate to these investigational levels if these limits are expressed in terms of a percentage of the current allowable limits; therefore, I would propose the following revision to Table L.1, "Investigational Levels": – Investigational Level I (mrem per calendar quarter): whole body, head and trunk, active blood forming organs, gonads - 125; lens of eye - 375; and skin or any extremity - 1250 – Investigational Level II (mrem per calendar quarter): whole body, head and trunk, active blood forming organs, gonads - 375; lens of eye - 1125; skin or any extremity - 3750.
NRC Staff Response: Table L.1 is part of a model procedure and, therefore, not required. The model procedures provide acceptable procedures for an occupational dose program. Licensees may either adopt the model procedures or develop their own procedures to meet the requirements. Nonetheless, we agree that Table L.1 should be revised to be consistent with Part 20 dose limits (e.g., the skin and extremity investigational levels should be the same, etc.). We used the following limits to revise the table: Investigation Level I when occupational dose reaches 10% of the annual limit and Investigational Level II at 30% of the annual limit.		

Location	Subject	Comment
Appendix L	Model Procedures for an Occupational Dose Program	Finally, we note that the new 10 CFR 35 eliminates many requirements for surveys (bioassays, Xe-133 traps, etc.). However, 10 CFR 20 still requires an active ALARA program. The effect is that the burden of proof is now on the users to demonstrate either that we do not need to make a particular survey or that we are making adequate surveys to ensure that no one is being exposed excessively. When we are inspected neither we nor the inspectors can merely appeal to the regulations. We must demonstrate to the inspector's satisfaction that we have an adequate ALARA program in place. We are concerned that this subtle distinction between parts 35 and 20 may be missed, especially in smaller institutions. We ask that the NRC, perhaps in the replacement of Reg Guide 10.8, make clear the requirements of 10 CFR part 20.
NRC Staff Response: The discussion of deletion of survey requirements from 10 CFR Part 35 can be found in the Statements of Consideration for the Rulemaking. With regard to guidance on the ALARA concept, please refer to Item 1.2 in the NUREG. This section describes the requirements in 10 CFR 20.1101 and references several documents that provide the NRC staff position on ALARA.		

Location	Subject	Comment
N/A	Draft Regulatory Guide DG-0007	Draft Regulatory Guide DG-0007 was used to prepare a distribution license for F-18 fludeoxyglucose (FDG) for a clinical PET center. The guide was most useful. The guide and our application were well received by the State's Bureau of Radiation Protection. The NRC may or may not have had FDG in mind when the guide was prepared but it worked well for FDG. Its real worth is demonstrated by the fact that it isn't item specific and applies equally to byproduct as well as accelerator produced material.
NRC Staff Response: Draft Regulatory Guide DG-0007 has not been referenced in NUREG-1556, Volume 9, and therefore no response is necessary.		

Table Z.5 Comments Provided by the University of California, Los Angeles, Dated December 21, 1998.

Location	Subject	Comment
Appendix R	Model Procedure for Area Surveys	The "Acceptable Surface Contamination Levels in Unrestricted Areas" found in Table R.3 of draft NUREG-1556, Volume 9, are about 3-10,000 times more restrictive for the same radionuclide than for decommissioned licensees, which appear in Table I of *Federal Register* Volume 63, Number 222, Page 64134, "Acceptable License Termination Screening Values of Common Radionuclides for Building Surface Contamination." These should be the same or less restrictive for medical licensees. Additionally, why is there not a constant factor rather than an enormous range of factors between the two tables. Please send the scientifically valid analysis upon which Table R.3 is based. If there is no analysis, and it seems highly likely that there is not, please remove this section from the NUREG.
NRC Staff Response: Table I of *Federal Register* Volume 63, Number 222, Page 64134, "Acceptable License Termination Screening Values of Common Radionuclides for Building Surface Contamination" provides screening levels for specific radionuclides. This table does not include radionuclides traditionally used in medicine. We agree that the suggested trigger level documented in Table R.3 of 20 dpm/100 cm^2 set for I-125 and I-129 appears low. This value and other values in the table were chosen to be consistent with the values provided in guidance for release of facilities and equipment (Policy and Guidance Directive FC 83-23). However, consistent with the grouping used in Table R.2, I-125 was moved to be grouped with I-131. Additionally, transuranics and I-129 were deleted from this table, because medical licensees do not normally use transuranics or unsealed I-129.		

Table Z.6 Comments Provided by the University of California, Dated November 10, 1998.

Location	Subject	Comment
Entire Document	Use of Guide	• The new draft "Consolidated Guidance about Materials Licenses," NUREG-1556, Volume 9 is a well-developed guidance and resource document. However, it is extremely important that this be adopted as a "guide" and that the license reviewers be instructed to treat it as such. The licensees must not be asked, as the past practice, to either commit in following the "guide" or submitting alternate procedures. It should simply be a guide for those who need advice. • Most modern equipment has manufacturers recommended quality control testing which is superior to certain of procedures in the guide, which are now obsolete.

NRC Staff Response:

- We believe that NUREG-1556, Volume 9, is risk-related and performance-based. NRC recognizes the low risk associated with many licensed activities and the ability of medical licensees to develop safe procedures without direct NRC involvement. Because of this, the guidance in Volume 9 was designed to reduce the amount of detailed information that a licensee is required to submit to NRC for review during the licensing process. The adequacy of the licensee's procedures, implementation of the procedures, and the ability of the licensee through these procedures to meet specific performance indicators, will be evaluated during inspections.
- More specific examples would be helpful. The model procedures were developed using multiple references, including documents issued by ANSI, ICRP, NCRP, and AAPM. Additionally, we have incorporated several clarifications to these procedures based on specific comments supplied by stakeholders.

Location	Subject	Comment
Section 8.21	Radiation Protection Program	NRC form 313, included in Appendix B of NUREG-1556, Volume 9, is supposedly intended to eliminate the previous requirement for detailed procedures. Item 10, "Radiation Protection Program," however, amplifies the concerns regarding the Commission's continued request for detailed and prescriptive procedure. Draft NUREG-1556, Volume 9, page 78, requires the license[e] to submit information on the proposed radiation protection program to minimally include the following items (as applicable): Audit Program, Leak Tests, Operating and Emergency Procedures, Material Receipt and Accountability, Area Surveys, Occupational Dose, Public Dose, Transportation, Minimization of Contamination, Mobile Nuclear Medicine, Procedures for Administrations Requiring WDs. This appears a simple shifting of commitments from the previous format of a checklist to submitting the information as a text. It is not a change in philosophy as discussed during the San Francisco workshop (August 19-20, 1998), nor is it compatible with the written documents distributed by the Commission. It is business as usual, provide details as part of the license application and be held to it as part of the license, and deviations are either violations or need pre-approval, prescriptive rather than performance-based criteria. The only shift is now the licensee has to define the prescriptive details, which will be used, presumably this qualifies as non-Commission prescribed details. The Commission must move away from this degree of prescriptive licensing in "action" as well as in words. The Commission must define the criteria such as maximum permissible occupational doses, acceptable contamination levels, waste disposal criteria, etc. and allow the licensee to develop their own criteria internally to achieve the prescribed goals. To continue with asking detailed procedural submittal defeats the entire process defined even in the "risk informed" approach.

Location	Subject	Comment
NRC Staff Response: Section 8.21, Item 10, states that the applicant/licensee should consider the following functional areas (Audit Program, Leak Tests, etc.). The section refers the applicant to Appendix C, which explains when detailed information must be submitted for a license. Of the 11 items discussed in the comment, only two require submitting detailed procedures. Many additional items require procedure development by the licensee without NRC review prior to licensing. Therefore, the licensee is given flexibility in developing and revising procedures.		

Table Z.7 Comments Provided by National Physics Consultants, Ltd, Dated November 12, 1998.

Location	Subject	Comment
Entire Document	Submission of Radiation Safety Procedures	Regarding the direction of the proposed changes, we agree with the goal to make Part 35 and the licensing process less prescriptive. Some of the current requirements in Regulatory Guide 10.8 are excessive for smaller facilities. A lot of time and effort has gone into complying with the more prescriptive requirements but resulted in no benefit to the radiation safety program. Further, the prescriptiveness prevented reasonable variations in the more minor procedures and record-keeping documents that have no real impact on the radiation safety program. Giving more latitude to the licensees in these areas is admirable. We agree that it is unnecessary to submit as many radiation safety procedures in the licensing process. A lot of time was unnecessarily spent arguing with license reviewers about minor details in these procedures. And a lot of facilities were required to accept procedural details that have no safety impact and are excessive for the particular facility. However, these details are considered necessary by the license reviewer simply because the detail is in the licensing guide and the reviewer is uncomfortable accepting alternatives. In general, we agree and support the changes from Regulatory Guide 10.8 that have been incorporated in this NUREG.
NRC Staff Response: No response necessary.		

Location	Subject	Comment
Section 8.16	Figure 8.8: Facility Diagram for Nuclear Medicine Suite	In Section 8.16, Facility Diagram, it is stated that the rooms used to confine patients for radiopharmaceutical therapy or manual brachytherapy treatments be included in the application. This is inappropriate for facilities that do not perform a lot of these procedures. Many facilities do not have a specified room for these therapies, but identify the room prior to each therapy. Further, in most facilities, including those facilities which have identified preferential rooms to be used, the rooms are not used exclusively for these therapies. There is sufficient guidance available on selecting rooms for these therapies and on assuring that radiation levels outside the room are within limits. The statement to submit diagrams of therapy rooms should be qualified to specify those rooms which are dedicated to these therapy procedures.
NRC Staff Response: General requirements for issuance of specific licenses, under 10 CFR 30.33(a)(2), state that an application will be approved if the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property. This requirement concerns licensing and is appropriate in consideration of health and safety concerns. The statement to submit diagrams of therapy rooms should be specific to those rooms that are dedicated to radiopharmaceutical therapy or manual brachytherapy procedures. Diagrams of rooms proposed for therapy treatments will be submitted at the initial time of licensing. If additional patient rooms are used in the future, room diagrams should only be submitted if the room design (including shielding) and occupancy of adjacent areas are significantly different from the original diagrams provided. The guidance in this area has been revised to reflect this change.		

Location	Subject	Comment
Section 8.17	Radiation Monitoring Instruments	In Section 8.17 it is stated that the response in an application is to include the type, sensitivity and range of the survey instruments. This is more than necessary and goes counter to the new direction of Part 35 and this regulatory guide. A commitment to possess survey meters adequate to meet the requirements of Part 35 and Part 20 should be sufficient. This is reflected in the discussion of the reason 35.220 is being deleted presented in the August 13, 1998 *Federal Register* publication of the proposed rule to revise Part 35. Further, we should not need to get into discussions with license reviewers over what is the better instrument to use. This should be evaluated by inspectors on site. Often, the choice of instrument is a matter of preference, not that one meter works and another does not work. In the current licensing process, we do not identify survey meters. It seems to us there should be less of a need to identify survey meters in the proposed licensing process. Also, there are recommendations for survey equipment in Appendix I of the NUREG. If necessary, these recommendations can be expanded. In the same paragraph it is stated that the response in an application is to include what is done when the survey instrument is being calibrated or repaired. This request should be eliminated. It is the licensees responsibility to have the necessary equipment available. The licensee should be able to make that decision at the time it is needed to be made. Situations change, equipment availability changes, and needs change. If I were to write a license application today and had to address this question, I would list every solution I could think of (rental, loaner, etc.) to give the facility options. So why ask the question. Again, this question is not asked in the current licensing process and it should certainly not be asked in the future.
NRC Staff Response: General requirements for issuance of specific licenses, under 10 CFR 30.33(a)(2) state that the application will be approved if the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property. This requirement concerns licensing and is appropriate in consideration of the health and safety concerns. It is, therefore, mandatory for an application to include a description of the characteristics of the survey instruments. Replacement of survey instruments with comparable survey instruments is discussed in Section 8.21, and does not require a license amendment.		

Location	Subject	Comment
Section 8.18	Dose Calibrator and other Dosage Measuring Equipment	In Section 8.18 it is stated that the response in an application is to include the make and model of the dose calibrator. This is unnecessary for the same reasons as stated above for survey instruments, but more so. The make and model is totally irrelevant. Again this paragraph also asks what will be done if the dose calibrator is being repaired, etc. This is an unnecessary question for the same reasons as stated above for survey instruments.
NRC Staff Response: General requirements for issuance of specific licenses, under 10 CFR 30.33(a)(2), state that the application will be approved if the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property. This requirement concerns licensing and is appropriate in consideration of health and safety concerns. It is, therefore, mandatory for an application to include a description of the dose calibrator. Section 8.21 describes minor changes to the Radiation Protection Program and provides an example of replacement of instrumentation with comparable instrumentation, which does not require a license amendment.		
Section 8.23	Occupational Dose	In Section 8.23 film badges and TLDs are listed for personnel monitoring devices. Optically stimulated dosimeters should also be listed. Appendix L should also be so modified.
NRC Staff Response: It is not within the scope of this document to address specific manufacturers of personnel monitoring equipment. However, optically stimulated dosimeters have become increasingly popular among licensees. Optically stimulated dosimeters will be incorporated into Section 8.23 because the monitor is NVLAP-approved. The first sentence of the fifth paragraph under discussion has been revised to read "If external dose monitoring is necessary, the applicant should describe the type of personnel dosimetry, such as film badges, optically stimulated luminescence dosimeters (OSL) or thermoluminescent dosimeters (TLDs), that personnel will use." Additionally, the following revision was made to the first full paragraph on page L-3: "External dose is determined by using individual monitoring devices such as film badges, optically stimulated luminescence dosimeters (OSL), or thermoluminescent dosimeters (TLDs)."		

Location	Subject	Comment
Appendix I	Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program	• In Appendix I a sodium iodide probe is recommended for detection of I-125, etc. A thin-window GM probe (pancake or thin end-window) is very adequate. The detection efficiency for thin-window GM's for I-125 is similar to that of scintillation probes. The additional cost of a NaI probe is not justified. A thin window will detect I-125 at a level sufficient to meet Part 20 requirements. Wipe testing can be used to evaluate removable contamination. The recommended equipment should include thin window GM's as acceptable. • Also in Appendix I, it is stated that, for medium to high energy gamma emitters, a GM is acceptable, but a NaI probe is preferred. While a NaI probe is more sensitive, it is more difficult to calibrate, more difficult to interpret results due to extreme energy dependence, more cumbersome to use, and more costly. After years of experience, it is clear that a GM is sufficiently sensitive to meet regulatory requirements. Again, removable contamination should be evaluated by wipe tests. We strongly request that the statement that NaI probes are preferred be removed.

NRC Staff Response:

- The third paragraph under Equipment Selection on I-1 has been changed to read "Low energy gamma emitters, such as I-125, can be detected with a sodium iodide (NaI) probe or a thin window GM probe (pancake or thin end-window). If the sodium iodide probe possesses a thin window and thin crystal, the detection efficiency is approximately 20%. If a pancake or thin end-window GM probe is used, the detection efficiency is significantly lower, and care should be taken to ensure that the GM probe is capable of detecting the trigger levels."
- The fourth paragraph under Equipment Selection on I-1 has been changed to read "Medium-to high-energy gamma emitters, such as I-131, can be detected with either GM or sodium iodide probes, depending on the required sensitivity. In general, the sensitivity of GM probes is much lower than for sodium iodide probes."
- Additionally, a table similar to that found in "The Health Physics & Radiological Health Handbook, Revised Edition, 1992" will be added to the NUREG to assist applicants in the proper selection of instruments.

Location	Subject	Comment
Appendix I	Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program	In Appendix I, it is suggested that well counters used for wipe test analysis and uptake probes used for bioassays have their efficiencies evaluated annually. The efficiency needs to be determined initially and occasionally as needed (such as after repair), but not on any specified frequency. More importantly, an energy calibration/check should be performed each day of use to correct for any gain shifts and a constancy check should be performed each day of use with a long lived source. Equipment on which the results of these two checks are satisfactory will not have a change of efficiency. Also, these checks assure the efficiency has not changed daily as opposed to annually. Please modify these sections. It is actually more important to periodically check energy resolution and chi-square, as these factors are sensitive indicators of equipment failure, are more likely to change than efficiency, and can have as great an effect on wipe test results as a change in efficiency.
NRC Staff Response: Because most well counters and uptake probes are of the NaI(Tl) variety, degradation of the crystal over time can dramatically effect the efficiency of the instrument. The model procedure provides for an annual efficiency determination. However, the licensee may adopt a different frequency as long as the instrumentation is calibrated periodically, in accordance with 10 CFR Part 20. Appropriately calibrated instrumentation is necessary for surveys, including: package wipe tests, bioassays, leak tests, and area contamination wipes. We agree that a daily check of the instrument is beneficial in identifying instrumentation problems early and have added this to the model procedure.		

Location	Subject	Comment
Appendix J	Model Procedures for Dose Calibrator Calibration	In Appendix J: • Under constancy, there is a statement that "We will consider the use of two or more sources..." This statement should be removed. First, there is no physical reason to use two sources for constancy. It is a misconception that a second source is of value. After evaluating thousands of dose calibrators, we have never seen a case where a change in constancy has been seen with one source but not a second source. Also, as the statement says "We will consider...", there is no requirement to do anything and the statement can be ignored. There is no value in the statement and it is often counterproductive. Facilities are occasionally put in the position to defend the use of only one source to inexperienced inspectors. • Under accuracy in Appendix J, there is the statement "We will consider using at least one reference source whose activity is within the range of activities normally assayed." The function inferred is provided in the linearity check. If there is a proven need for a source in this activity range, then the statement should be more definitive. Otherwise it should be removed. We would not recommend this higher activity source as it is of no value and only adds to costs.

NRC Staff Response:

- The Constancy paragraph on page J-1 has been changed to "Constancy means reproducibility in measuring a constant source over a long period of time. We will assay with a relatively long-lived dedicated check source such as Cs-137, Co-60, cobalt-57 (Co-57)[2], or radium-226 (Ra-226)[2] using a reproducible geometry each day before using the calibrator."
- The Accuracy paragraph on page J-5 has been revised to "Accuracy means that, for a given calibrated reference source, the indicated activity (e.g., mCi) value is equal to the activity value determined by NIST or by the supplier that has compared that source to a source that was calibrated by NIST, corrected for decay. Certified sources are available from NIST and from many radionuclide suppliers."

Location	Subject	Comment
Appendix J	Model Procedures for Dose Calibrator Calibration	In Appendix J, under linearity, shield method, the methodology for data analysis is unduly complicated. The concept of determining the "equivalent decay time" of a sleeve is from Regulatory Guide 10.8. That view was the way the author of 10.8 looked at the sleeve method at that time. The more straightforward analysis with the sleeves is to simply determine the ratios of the readings between sleeves. If a sleeve reduces the reading by a factor of, say, 10 on day one, it should always reduce the reading by a factor of 10. Both suppliers of sleeve kits recommend a calculational method using ratios, not equivalent decay time. This is a much simpler technique. Also, the calculational method in Appendix J is incomplete. A couple of steps are missing.
NRC Staff Response: The model procedure was revised to ensure that the essential objectives of the manufacturer's guidance were incorporated. The ratio dependence statement was incorporated.		
Appendix L	Model Procedures for an Occupational Dose Program	The requirement for providing personnel dosimetry to minors and to declared pregnant workers must be increased to 0.1 rem. This was a recent change in Part 20.
NRC Staff Response: The appendix and Section 8.23 were revised to incorporate the changes in 10 CFR 20.1502.		

Location	Subject	Comment
Appendix R	Model Procedure for Area Surveys	The acceptable removable surface contamination level in unrestricted areas for I-125 is stated at 20 dpm/100 cm^2 in Table R.3. This is an excessively low value. It is below most facilities MDA's for their counting equipment. There is no justification for this value to be so low. The ALI's (as a comparator) for I-125 and I-131 are nearly the same. We suggest the values for I-125 be set equal to the values for I-131.
NRC Staff Response: We agree that the suggested trigger level documented in Table R.3 of 20 dpm/100 cm^2 set for I-125 and I-129 appears low. This value and other values in the table were chosen to be consistent with the values provided in guidance for release of facilities and equipment (Policy and Guidance Directive FC 83-23). However, consistent with the grouping used in Table R.2, I-125 was moved to be grouped with I-131. Additionally, transuranics and I-129 were deleted from this table, since medical licensees do not normally use transuranics or unsealed I-129.		
Appendix V	Guidance for Mobile Services	In Appendix V, page V-2, a statement is made that, for Class 2 mobile services, a description and diagram of the client site must be provided. This is inappropriate for diagnostic nuclear medicine procedures. For Class 2 nuclear medicine providers, the material is taken into the facility by the mobile service, used, and then all radioactive material, including waste, is removed. A survey is performed to assure no residual contamination remains. There is no need to list each site. Also, the sites to which services are provided are very variable. A requirement to list each site would be counterproductive to the benefits of a mobile service.
NRC Staff Response: The model procedures for mobile diagnostic service providers were revised to delete the requirement to submit facility diagrams. Section 8.42 was revised accordingly.		

Table Z.8 Comments Provided by the University of Cincinnati, Dated November 10, 1998.

Location	Subject	Comment
Entire Document	Term "shall" versus "could"	Items within the guidance that are required by regulation should be so noted by using the word "shall." Items within the guidance that are not required by regulations should be so noted by using the word "could."
NRC Staff Response: Excluding the model procedures, we exercised the philosophy that information required by regulation is designated by using the word "shall" and items that are not required are designated by using the word "should." The term "will" is used in the model procedures to avoid ambiguity so that the licensee's staff clearly understands what is required by the procedure (if the licensee adopts the model procedure). However, we noted that in some cases, outside of the model procedures, the terms were incorrectly used and we have corrected these in the final version of the document.		
Entire Document	Non-submittal of licensing information	Most of the recommended wording for license applications is very general, i.e., a statement by the applicant indicating agreement to comply with a specific regulation. Since this allows a licensee to modify the Radiation Safety Program in a more timely, and less expensive manner, we like this approach, with reservations. We are concerned that by not requiring the licensee to provide specific procedures inspectors will cite for errors or incidents, no matter how minor and how conceivable with foresight. If the NRC uniformly changes to a licensee oversight that is based on "consistent compliance with regulations (to provide) reasonable assurance that licensed activities will be conducted safely" (page 3-1 of NUREG-1556, Volume 9), the concern should be unfounded and/or known.
NRC Staff Response: This appears to be a comment on the inspection process and inspection procedures to be used by NRC in conjunction with the revised 10 CFR Part 35 and not the NUREG, per se. We believe that NUREG-1556, Volume 9, is risk-related and performance-based. NRC recognizes the low risk associated with many licensed activities and the ability of medical licensees to develop safe procedures without direct NRC involvement.		

Location	Subject	Comment
Section 4	Applicable Regulations	On page 4-1 the statement in the box about compliance with DOT regulations should include the fact that NRC requires compliance with DOT regulations whether the transportation is or is not done "in commerce." This distinction is often not understood and/or known.
NRC Staff Response: 10 CFR Part 71 requires that licensees who transport licensed material on public highways or who may offer such material to a carrier for transport comply with the applicable requirements of the DOT that are found in 49 CFR Parts 170 through 189. The regulation does not include an exemption for licensed material that is transported out of commerce, and therefore, no revision is necessary in the NUREG.		
Section 7	License Fees	On page 7-1, the second paragraph talks about exemption from fees. Unless there are medical licensees who are exempted from fees, the mention of exemptions is not necessary.
NRC Staff Response: Most, but not all, NRC licensees are subject to fees. Therefore, the mention of exemptions in this section is applicable.		
Section 8.5	Radioactive Material	Page 8-6 indicates applicants must list the manufacture[r]'s name and model number for ALI brachytherapy sources to be used. For standard brachytherapy this is not practical. A recent order for I-125 seeds determined individual seeds and seeds on a ribbon had different model numbers, even though the seeds used were exactly the same. We suggest that licensees be allowed a more generic approval for standard brachytherapy sources.
NRC Staff Response: 10 CFR 30.32(g) states that an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source must either: • Identify the source or device by manufacturer and model number as registered with the commission under 32.210 of this chapter or with an Agreement State; or • Contain the information identified in 32.210(c). The sealed source and device registry is catalogued according to the manufacturer's name and model number. Therefore, this information must be provided.		

Location	Subject	Comment
Section 8.8	Purposes for Which Licensed Material will be Used	The NUREG states "unsealed byproduct material in therapy involves the administration of a radiopharmaceutical,..., to diagnose, treat or palliate a particular disease." The statement is either unclear or wrong. Written directive dosages may be used to diagnose disease; however, therapy dosages are not used to "diagnose" disease. The statement needs to be changed to apply to written directive dosages or the word "diagnose" needs to be removed.
NRC Staff Response: The word "diagnose" was deleted from text referring to unsealed byproduct material in therapy administrations.		
Section 8.9	Individual(s) Responsible for Radiation Safety Program and Their Training and Experience	On page 8-19, the last paragraph, the NUREG states, "Senior management should delegate to the RSO and, if applicable, the RSC in writing, sufficient authority..." Though not required by regulation, the University of Cincinnati believes this is a good requirement.
NRC Staff Response: No response necessary.		
Section 8.26	Operating and Emergency Procedures	Criteria states "Before using licensed material, licensees must do the following: Develop, implement and maintain specific operating and emergency procedures." Maintaining the procedures should occur during use not before use.
NRC Staff Response: NUREG-1556, Volume 9, was revised to reflect the distinction.		
Sections 8.27-8.44	Phrase "No response is Necessary"	In some sections, e.g., Ordering and Receiving, Sealed Source Inventory and Safety Procedures, the NUREG indicates there is no response from the applicant for this item. Since there are regulatory requirements associated with the item and the NRC is addressing the item why is there "no response necessary"?
NRC Staff Response: 10 CFR 20.1906 does not require the licensee to develop procedures for ordering or receiving packages. Additionally, the various other sections that do not require a response are based on regulations that do not specifically require development of procedures. Therefore, no response by the applicant during the licensing process is required.		

Location	Subject	Comment
Section 8.31	Use Records	• This Section does not agree with the regulations as drafted. Specifically, this document indicates radiopharmaceutical dosage records are required to include: the radionuclide, the generic name or its abbreviation or trade name, and the patient's or human research subject's name and identification number if one has been assigned. However, the drafted regulations require the radionuclide (or the generic name or its abbreviation or trade name) and the patient's or human research subject's name or identification number if one has been assigned. • Requirements for brachytherapy use records should be individually bulleted like the radiopharmaceutical records. This will help licensees ensure they do not miss a required item. • Though it may seem unquestionable, it may be useful to indicate that brachytherapy inventory numbers must add up (i.e., temporary implants totals before and after should be equal; permanent implant total before should equal used and returned).
NRC Staff Response: • The NUREG was revised to be consistent with 10 CFR 35.2063. • The brachytherapy record requirements are bulleted. • A note to ensure that sources "add up" was included.		
Section 8.32	Leak tests	The first sentence on page 8-61 should make it clear that a contractor performing leak testing must be approved (or licensed) by the NRC or Agreement State.
NRC Staff Response: The NUREG was revised to include the statement that a contractor must be authorized by NRC or an Agreement State.		

Location	Subject	Comment
Section 8.33	Area Surveys	The 5th bullet on page 8-62 indicates licensees should consider performing a radiation survey of the room of a patient undergoing temporary brachytherapy after implantation to look for a dislodged source. In most cases when the afterloading is done in the room this survey would be impossible due to the radiation being emitted from the patient.
NRC Staff Response: The suggested survey to ensure accountability does not have to be an ambient exposure rate survey with a survey instrument, but may instead include a visual check to ensure that a source has not been misplaced. This distinction was added.		
Section 8.35	Safe Use of Unsealed Licensed Material	On page 8-63, last paragraph, it is the quantity of volatile or potentially volatile radioactive material that needs to be assessed for air emissions, not the quantities of (all) radioactive materials.
NRC Staff Response: The NUREG was revised to reflect the change in the last paragraph, line 3 from "radioactive material" to "volatile or potentially volatile licensed material."		
Section 8.44	Waste Management	On page 8-82, why is such detail required for compaction of radioactive waste at medical institutions? Is there a regulation requiring this detail in an application? The compaction of radioactive waste, such as generated at a medical institution, has few, if any, safety issues beyond those encountered with the use of the material. Compactors do not make the radioactive material volatile and other types of airborne radioactive material from the compaction of medical institution are not probable.
NRC Staff Response: Compacting does not make radioactive material volatile, but volatile (and non-volatile, dispersible) materials can be released during compaction. 10 CFR 20.1101 requires a licensee to develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of this part. Subpart K of 10 CFR Part 20 includes waste disposal. Additionally, 10 CFR 30.33(a)(2) requires that an applicant's proposed equipment and facilities are adequate to protect health and minimize damage to life and property.		

Location	Subject	Comment
Section 8.44	Waste Management	• On page 8-83, the second paragraph, removal or obliteration of caution radioactive material is only required for radioactive waste that is disposed of in the regular trash after decay-in-storage. Removal or obliteration of the labels on waste that is to be disposed of as radioactive is not a good health physics practice, as it has the potential for unnecessarily increasing radiation exposure. The removal or obliteration of the label should be a guidance under "DIS" not a general guidance for waste disposal. • On page 8-83, the last paragraph, return to the vendor is not the only option for brachytherapy sources. They could be disposed of at a licensed LLRW site, at a significant cost, or transferred to another licensee.
NRC Staff Response: • The NUREG was changed to clarify that removing or obliterating labels from empty or adequately decayed containers going to non-radioactive trash must be done in accordance with 10 CFR 35.92 and 10 CFR 20.1904. • The language found in the NUREG allows for transfer of sources to an authorized recipient. Therefore, this does not limit the return of sources to the vendor.		
Appendix L	Model Procedures for an Occupational Dose Program	Since dose limits have been changed from quarterly to annual only, why weren't the recommendations for external (page L-4) ALARA investigational levels changed from quarterly to annual?
NRC Staff Response: We agree with this comment and have revised the guidance accordingly.		

Location	Subject	Comment
Appendix R	Model Procedure for Area Surveys	• There was not sufficient time to compare the contamination levels for unrestricted areas listed in appendix R of this guide with those listed in the guidance for unrestricted release during decommissioning. The levels should be comparable. • The contamination level for I-125 and I-129 in Table R.3 appears at first glance to be overly restrictive. The radiation risks from these radionuclides are more equivalent to the other isotopes of iodine than transuranics. In comparison, if the group listing on page R-6 is used, I-129 is significantly a lower hazard than the other isotopes of iodine. (Note: I-125 is not included in the group listing on page R-6; however, the University of Cincinnati would expect it to be included in group III or IV.)
NRC Staff Response: Table I of *Federal Register* Volume 63, Number 222, Page 64134, "Acceptable License Termination Screening Values of Common Radionuclides for Building Surface Contamination" provides screening levels for specific radionuclides. This table does not include radionuclides traditionally used in medicine. We agree that the suggested trigger level documented in Table R.3 of 20 dpm/100 cm^2 set for I-125 and I-129 appears low. This value and other values in the table were chosen to be consistent with the values provided in guidance for release of facilities and equipment (Policy and Guidance Directive FC 83-23). However, consistent with the grouping used in Table R.2, I-125 was moved to be grouped with I-131. Additionally, transuranics and I-129 were deleted from this table, because medical licensees do not normally use transuranics or unsealed I-129. Also, I-125 was added to Group 2 in Table R.4, which is consistent with its ranking in the other tables of this appendix.		
Appendix W	Transportation	More detailed guidance for DOT is recommended. Some licensees unknowingly miss DOT requirements. Guidance that applies the regulations to situations commonly found with medical licensees, versus just listing applicable regulations, would be very beneficial.
NRC Staff Response: 10 CFR Part 71 requires that licensees who transport licensed material on public highways or who may offer such material to a carrier for transport, comply with the applicable requirements of the DOT that are found in 49 CFR Parts 170 through 189. To further assist licensees in locating transportation requirements, the following statement was added: "For additional transportation information, licensees may consult DOT's 'A Review of the Department of Transportation Regulations for Transportation of Radioactive Materials' or contact the DOT, at http://www.dot.gov."		

Table Z.9 Comments Provided by Allegheny University Hospitals, Dated November 1, 1998.

Location	Subject	Comment
Appendix G	Documentation of Training and Experience	Remodeling needs to be accomplished of the Training and Experience Documentation forms in Appendix G. The term "clock hours" should only refer to the 80/40 required hours of training by the rule. Related radiation exam scores should probably read "name of approved radiation safety test passed" and scores should be reported only pass/fail. Point number 6 on "Formal Training" almost certainly relates to therapy. There should be separate forms for diagnostic documentation versus therapy documentation to keep the approach risk-based. NRC form 313B once again asks for "clock hours" of specific isotope use which is not a proposed requirement of the rule. The safety experience for diagnostic isotopes is similar and should be able to be extrapolated to all isotopes in 35.200.

NRC Staff Response:

- The term "didactic training" was revised to "classroom and laboratory training." Therefore, "clock hours," as used under item #4, refers to the hours spent in the classroom and laboratory.
- Because an exam component has been deleted from 10 CFR Part 35, documentation of the exam was deleted from the forms.
- Item #6 on NRC Form 313A applies to all 10 CFR 35.400 and 10 CFR 35.600 medical users. To clarify, a note to this effect was added.
- Form 313B documents the work experience, including the number of cases and hours spent involved in the cases, and therefore assists the licensee and the regulatory body in determining whether appropriate experience has been gained by the prospective user.

Table Z.10 Comments Provided by the American Society of Nuclear Cardiology, Dated November 12, 1998.

Location	Subject	Comment
Appendix G	Documentation of Training and Experience	Ministerial changes are necessary to NRC forms 313A and 313B: • "Clock hours" should clearly refer only to the required 120 hours of radiation safety training. • "Related radiation exam score" should read "Approved Radiation Safety Test Passed" and results should be reported pass/fail. • There should be separate forms for diagnostic versus therapy to match a risk-based approach. • Clarification of "organization approving program" is necessary. • Demonstration of individual isotope clock hours is not part of the rule. We assume the safety principles can be extrapolated to all isotopes in 35.200.

NRC Staff Response:

- The term "didactic training" was revised to "classroom and laboratory training." Therefore, "clock hours," as used under item #4, refers to the hours spent in the classroom and laboratory.
- Because an exam component has been deleted from 10 CFR Part 35, documentation of the exam was deleted from the forms.
- Because most items refer to both diagnostic and therapy prospective users, an additional form was not created.
- An example of the ACGME has been given for "organization approving program."
- Form 313B documents the work experience, including the number of cases and hours spent involved in the cases, and therefore assists the licensee and the regulatory body in determining if appropriate experience has been gained by the prospective user.

Table Z.11 Comments Provided by The Community Hospital, Undated.

Location	Subject	Comment
Entire Document	Issuance of NUREG in Final	The issuance of the NUREG before completing the revision of 10 CFR Part 35, is inappropriate.
NRC Staff Response: NRC sought to develop the licensing guidance NUREG concurrently with the proposed regulation in an effort to better serve the regulated community. This method allowed the regulated community to comment on the proposed rule and the proposed licensing guidance simultaneously. Although this method has its drawbacks, NRC believes that the benefits of this method outweigh the drawbacks. Additionally, before the final NUREG was issued, all references to 10 CFR Part 35 were reviewed to ensure that statements made in the NUREG reflect the final regulatory requirements.		

Table Z.12 Comments Provided by Paul J. Early, Dated December 17, 1998.

Location	Subject	Comment
Appendix R	Model Procedure for Area Surveys	The 200 dpm/100 cm^2 wipe test requirement cannot be justified. Please refer to the calculations that were presented at the program in Rockville, MD by Dr. Carol Marcus.
NRC Staff Response: Table I of *Federal Register* Volume 63, Number 222, Page 64134, "Acceptable License Termination Screening Values of Common Radionuclides for Building Surface Contamination" provides screening levels for specific radionuclides. This table does not include radionuclides traditionally used in medicine. We agree that the suggested trigger level documented in Table R.3 of 20 dpm/100 cm^2 set for I-125 and I-129 appears low. This value and other values in the table were chosen to be consistent with the values provided in guidance for release of facilities and equipment (Policy and Guidance Directive FC 83-23). However, consistent with the grouping used in Table R.2, I-125 was moved to be grouped with I-131. Additionally, transuranics and I-129 were deleted from this table, because medical licensees do not normally use transuranics or unsealed I-129.		

Table Z.13 Comments Provided by Robert Forrest, CHP, Dated November 11, 1998.

Location	Subject	Comment
Appendix R	Model Procedure for Area Surveys	I-125 is included with I-129 and transuranics in Table R.3, "Acceptable Surface Contamination Levels in Unrestricted Areas in dpm/100 cm^2." Some justification for the inclusion of I-125 with transuranics should be given.
NRC Staff Response: We agree that the suggested trigger level documented in Table R.3 of 20 dpm/100 cm^2 set for I-125 and I-129 appears low. This value and other values in the table were chosen to be consistent with the values provided in guidance for release of facilities and equipment (Policy and Guidance Directive FC 83-23). However, consistent with the grouping used in Table R.2, I-125 was moved to be grouped with I-131. Additionally, transuranics and I-129 were deleted from this table, because medical licensees do not normally use transuranics or unsealed I-129.		
Appendix U	Release of Patients or Human Research Subjects Administered Radioactive Materials	Example 2, Thyroid Cancer, in Supplement B to Appendix U shows a release calculation for the administration of 200 mCi of I-131 using the standard assumptions. In the example the patient is deemed releasable because the calculated dose to a member of the general public is 453 mrem and therefore less than the 500 mrem limit. This calculation does not include a contribution for internal dose which is shown in example 4, Internal Dose. This example states that internal doses may be ignored in the calculations if they are likely to be less than 10% of the external dose. In the 200 mCi dose example the dose from internal is 106 mrem which is 23.4 % of the dose from external. Because the internal is greater than 10% of the external, the internal should be included in the calculation. The patient receiving a 200 mCi dose would therefore not be releasable based on the standard assumptions. Either the example should be corrected or the internal requirement should be modified.
NRC Staff Response: We agree with this comment and have revised Example 2 to use 150 millicuries instead of 200 millicuries. According to the calculation, this would result in an estimated dose of 340 millirem. We have also added a fifth example on how to calculate internal dose that includes a calculation for the internal dose using 150 millicuries. This results in an internal dose estimate of 80 millirem, and therefore, a total dose of 420 millirem.		

Table Z.14 Comments Provided by the Health Physics Society, Dated December 14, 1998.

Location	Subject	Comment
Entire Document	Issuance of NUREG in Final	The issuance of the NUREG is inappropriate before completing the revision of 10 CFR Part 35.
NRC Staff Response: NRC sought to develop the licensing guidance NUREG concurrent with the proposed regulation in an effort to better serve the regulated community. This method allowed the regulated community to comment on the proposed rule and the proposed licensing guidance simultaneously. Although this method has its drawbacks, NRC believes that the benefits of the method outweigh the drawbacks. Additionally, before the final NUREG was issued, all references to 10 CFR Part 35 were reviewed to ensure that statements made in the NUREG reflected the final regulatory requirements.		

Table Z.15 Comments Provided by the Illinois Department of Nuclear Safety, Dated December 16, 1998.

Location	Subject	Comment
Section 8	Contents of an Application	• Section 35.12 of the proposed regulation requires a separate license application for each medical use of byproduct material. For your consideration, IDES allows a facility to submit one license application covering several uses of radioactive material, as long as such activity is under one management and one qualified RSO. This consolidates the licensing and inspection activities for a particular site, and allows licensees to submit one set of procedures for generic issues such as emergency notifications, waste handling, and receipt, use and transfer. • Section 8 of the medical NUREG contains information to be included in an application. It is unfortunate that the application form is not detailed enough for licensees to use as a checklist. For example, licensees could have the option to indicate the use of a model program presented in an appendix or develop their own procedure. Additional "check boxes" could be created for standard uses of radioactive material.
NRC Staff Response: • The comment appears to address the proposed 10 CFR 35.12 and not the NUREG, per se. However, before the final NUREG was issued, all references to 10 CFR Part 35 were reviewed to ensure that statements made in the NUREG reflected the final regulatory requirements. • A checklist was added to Appendix C as requested.		

Location	Subject	Comment
Entire Document	Section Numbering	Pages 8-6, 8-8 and 8-11 were confusing because they all have the heading "ITEM 5" yet cover three different subjects. The application form and page 8-6 match with "ITEM 5: RADIOACTIVE MATERIAL." Unfortunately, page 8-8 contains requirements for financial surety. This requirement should be in a separate location, and maybe even tied to a separate item on the application form. Page 8-11 addresses "ITEM 5: SEALED SOURCES AND DEVICES" which appears to be a subset of "ITEM 5: RADIOACTIVE MATERIAL" on the application form. Maybe if the sections were numbered as 8.5A and 8.5B, it would be clearer that Section 8 deals with the content of an application, the number after the decimal refers to the appropriate section of the application, and the alpha characters are subsections for those application sections. This same comment refers to the multiple ITEM 7s, 9s and 10s.
NRC Staff Response: The section numbering chosen reflects the numbering used in Volume 1 of the NUREG-1556 series. A key component of the numbering is the Item Number taken from the license application (NRC Form 313). Therefore, whenever "Item 5" is listed, the section refers to Item 5, "Radioactive Material," on NRC Form 313.		
Section 8.7	Sealed Sources and Devices	On page 8-11 of the NUREG, the Criteria for sealed sources and devices requires applicants to submit information, yet the Response from Applicant states, "No response is necessary." This should be changed to: "The applicant shall submit the information as described above." Consider a generic provision in the NUREG that would allow possession of any radionuclide in sealed form, provided that such source or source/device combination has been approved by the FDA for medical use, and has been evaluated by the NRC or an Agreement State and is listed in the Registry of Sealed Sources and Devices. The maximum activity would be limited by the amount authorized on the evaluation sheet.
NRC Staff Response: The response to Section 8.7 was revised to read: "If possession of sealed source(s) or device(s) is requested, the applicant shall submit the information as described above."		

Location	Subject	Comment
Section 8.14	Training for Individuals Working in or Frequenting Restricted Areas	On page 8-29, training requirements, the NUREG states that "All individuals working with or around licensed materials should receive training..." The paragraph continues to explain that in addition, if the individual is likely to receive doses over 1 mSv in a year, they must also have training as required by 10 CFR 19.12. Appendix H, however, states that personnel shall be instructed before starting duties around radioactive materials and during annual refresher training. This Appendix appears to be establishing a requirement different from those in the regulations. 10 CFR 19 appears to only require training if an individual is likely to receive doses in excess of 1 mSv, and does not mention refresher training requirements. The rules should be modified to specify the actual intent of the regulations, rather than try to clarify the intent through guidance.
NRC Staff Response: 10 CFR 19.12 requires training of individuals who work in the vicinity of licensed material and, in the course of employment, are likely to receive 100 millirem in a year. 10 CFR 35.27, 35.310, 35.410, and 35.610 require additional instruction for medical personnel. In addition, it is prudent for licensees to train all individuals involved with activities with licensed material, and therefore, we have included a suggestion that these individuals be trained (see Section 8.14). Appendix H of the NUREG provides a model training program that includes training for all personnel who work in the vicinity of radioactive materials. The model procedures provide acceptable procedures for training. Licensees may either adopt the model procedures or develop their own procedures to meet the requirements, as applicable.		
Section 8.21	Radiation Protection Program	Item 10 on the application and the corresponding sections in the NUREG contain many instances where no response is necessary from a licensee, or a licensee must commit to developing and implementing certain procedures. Rather than require licensees to state that they will develop procedures, IDES intends to review those procedures as part of the licensing process. It is more important to ensure a licensee has adequate procedures in place before radioactive material is used, rather than discover during an inspection that there are significant problems due to inadequate procedures.
NRC Staff Response: In this NUREG, NRC recognizes the low risk associated with many licensed activities and the ability of medical licensees to develop safe procedures without direct NRC involvement.		

Location	Subject	Comment
Appendix L	Model Procedures for an Occupational Dose Program	Appendix L contains information about bioassay programs. Specifically, Page L-7 states, "For each patient or human research subject receiving radiopharmaceutical therapy, the licensee should measure the thyroid burden of each individual who prepares or administers a dosage of iodine-131 NaI..." It is unclear why an applicant should develop an internal bioassay program for those cases where I-131 is used, because it is unlikely, even under typical accident conditions, that an individual would exceed 10% of the regulatory limits. 10 CFR 20 requires monitoring of intakes if individuals are likely to receive greater than 10% of the ALI. Years of data gathered by medical facilities have demonstrated that individuals are not likely to exceed 10% of the ALI. Appendix L should either address the kinds of documentation that NRC would want the facility to have should it decide not to perform bioassays, or mention the fact that there are circumstances for which licensees may not need to perform bioassays.
NRC Staff Response: The detailed procedures were replaced with a referral to the appropriate Regulatory Guides and NUREG that cover this subject in greater detail.		

Table Z.16 Comments Provided by Mallinckrodt, Inc., Dated December 16, 1998.

Location	Subject	Comment
Entire Document	Term "should" versus "must"	Guidance documents should be written to provide the licensee a suggested way to deal with the NRC regulations. For this reason the guidance document should contain suggested language such as "could" and "may." NUREG 1556 contains "must" language that implies that the guidance document must be followed in order for the licensee to be in compliance. Most experienced nuclear medicine departments have developed outstanding practices to deal with radiation safety, often times superior to what is being proposed in the guidance document. This should be allowed, and encouraged. NUREG 1556 needs to be revised to provide for suggested compliance methods rather than mandatory methods.
NRC Staff Response: Except in the model procedures, we exercised the philosophy that information required by regulation is designated by using the word "shall" and items that are not required are designated by using the word "should." The term "will" was used in the model procedures to avoid ambiguity so that the licensee's staff clearly understands what is required by the procedure (if the licensee adopts the model procedure). However, we noted that in some cases outside the model procedures, the terms were incorrectly used and have corrected this in the final version of the document.		

Table Z.17 Comments Provided by Mobile Testing, Dated October 10, 1998.

Location	Subject	Comment
Appendix C	License Application Checklist	Table C.1 is an especially helpful checklist. This should also improve the completeness of submitted license applications increasing overall efficiency of all parties.
NRC Staff Response: No response necessary.		
Appendix R	Model Procedure for Area Surveys	The increase in the acceptable surface contamination level from 2000 to 20000 dpm/100cm^2 for Tc99m is appropriate. Equipment availability and calibration at the proposed level will be improved as discovery of possible contamination is unchanged.
NRC Staff Response: No response necessary.		

Table Z.18 Comments Provided by the Nuclear Energy Institute, Dated December 16, 1998.

Location	Subject	Comment
Entire Document	Issuance of NUREG in Final	NEI has not commented on the NUREG at this time as this document is based on the proposed rule. Given the significant changes to the rule recommended by NEI, we do not believe it to be useful to comment on the Standard Review Plan until the NRC has considered our proposed changes to the rule.
NRC Staff Response: NRC sought to develop the licensing guidance NUREG concurrent with the proposed regulation in an effort to better serve the regulated community. This method allowed the regulated community to comment on the proposed rule and the proposed licensing guidance simultaneously. Although this method has its drawbacks, NRC believes that the benefits of the method outweigh the drawbacks. Additionally, before the final NUREG was issued, all references to 10 CFR Part 35 were reviewed to ensure that statements made in the NUREG reflected the final regulatory requirements.		

Table Z.19 Comments from Public Meetings on 10 CFR Part 35.

Location	Subject	Comment
Entire Document	Terms "should" and "could" versus "shall"	The concern with the guidance document is, so many times, guidance documents are taken to be requirements. The inspector may say your procedure doesn't follow with the guidance document, therefore they turn around and cite you. Words like "shall" can go either way. "Shall" could mean should or "shall" could mean could. A guidance document should be guidance and should be filled with language such as "could," not language of "shall" and "should."
NRC Staff Response: Except for in the model procedures, we exercised the philosophy that information required by regulation is designated by using the word "shall" and items that are not required are designated by using the word "should." The term "will" was used in the model procedures to avoid ambiguity so that the licensee's staff clearly understands what is required by the procedure (if the licensee adopts the model procedure). However, we noted that in some cases outside the model procedures, the terms were incorrectly used and corrected this in the final version of the document.		
Section 1	Purpose of Report	Clarify the word "guide" or "guidance" in the regulations. Also, dealing with other regulatory agencies, state or local agencies, these guides often become de facto regulations. We need to go further with the guidance document. Why are the procedures requirements to begin with? There is no valid reason for most of them. The smaller institution does require some guidelines, however the guidelines have been so prescriptive in the past that there's a lot of concern. An experienced nuclear medicine department knows how to write their own procedures, they know how to do things properly. They don't need a guidance document. Who needs a guidance document is a new department or a department that's adding nuclear medicine.
NRC Staff Response: This appears to be a comment on the inspection process and inspection procedures to be used by NRC in conjunction with the revised 10 CFR Part 35 and not the NUREG, per se. As stated in Section 1, "Purpose of Report," the report provides guidance to an applicant in preparing a medical use license application. Therefore, we believe that this guidance will be useful to all medical applicants/licensees.		

Location	Subject	Comment
Section 1	Purpose of Report	• In terms of whether any guidelines are needed, it would be better to have the guidelines but to have them developed by people who are more knowledgeable in the field – for example, by members of AMP, ABS, et cetera. Then better guidelines will follow. • The licensees are feeling that they're going to be forced into accepting the model procedures. The procedures are terrible and medically very bad. They, health physics-wise, have no validation. Some of them are dangerous and against regulations of other regulatory agencies. You have to ask whether you need these procedures at ALI. The development of a procedure and a policy for what a technologist should do if they don't understand something – that's ridiculous. If a technologist doesn't understand something, they ask. There doesn't need to be a policy and procedure development. Neither do we need policies and procedures for the decrease in generation of radioactive waste. We don't accept these prescriptive and unacceptable directions on how to do things. The bottom line is if there hasn't been a safety issue, what are you even bothering with? There is no problem if no one is getting overdosed, if Part 20 is okay? When you talk about a performance standard, you mean things are safe. You have replaced precise, prescriptive regulation with vague, prescriptive regulation and you are calling it a performance standard and it is not.
NRC Staff Response: NRC sought to develop the licensing guidance NUREG concurrent with the proposed regulation in an effort to better serve the regulated community. This method allowed the regulated community to comment on the proposed rule and the proposed licensing guidance simultaneously. Although this method has its drawbacks, NRC believes that the benefits of the method outweigh the drawbacks. Additionally, we believe that NUREG-1556, Volume 9, is risk-related and performance-based. NRC recognizes the low risk associated with many licensed activities and the ability of medical licensees to develop safe procedures without direct NRC involvement. The model procedures were developed using multiple references, including documents issued by ANSI, ICRP, NCRP, and AAPM. We have incorporated several clarifications to these procedures based on specific comments supplied by stakeholders. We believe that licensees will find these model procedures useful when developing their own procedures.		

Location	Subject	Comment
Section 1	Purpose of Report	• NRC is following through with their usual methodology, which involves the 90-day period for public comment, regardless of the magnitude of the rule. I would recommend that the NRC follow through with their procedures and publish something, but just not make it a final rule. I also think that the NRC would serve the licensed community very well if a draft license application review document that would accompany the rule was published. • As the rule is about to change with the incorporation of public comments, the NUREG document would no longer make sense in many respects and, therefore, another NUREG document along with the new proposed rule-making should be published.

NRC Staff Response:

- This comment appears to apply only to the proposed revision of 10 CFR Part 35 and not to NUREG-1556, Volume 9. NRC accepted comments on the draft NUREG until finalized approximately 2 years later. We, therefore, believe that the period available for comment was sufficient. With regard to the comment on publishing a draft license application review document along with the rule, NUREG-1556, Volume 9 is this document.
- Before the final NUREG was issued, references to 10 CFR Part 35 were reviewed to ensure that statements made in the NUREG reflected the final regulatory requirements.

Location	Subject	Comment
Appendix J	Model Procedures for Dose Calibrator Calibration	• If you look at geometry, there's three different types. NRC addresses only the volumetric geometry changes in their particular NUREG. • The one area where the volumetric changes (geometry requirement) in the NRC regulations fall short is the fact that they assume that correction factors, which may be measured and usually are measured with tech-99m, are applicable across the board to all isotopes, and that's incorrect.

NRC Staff Response:

- Appendix J states that geometry independence means that the indicated activity does not change with volume or configuration. The model procedure considers both volume and configuration.
- Most nuclear medicine dosages involve technetium-99m. Therefore, it is prudent to perform geometry independence tests with the most frequently used radionuclide. However, we agree that the NUREG should address the issue of evaluating geometry variance for gamma emitters with energies significantly different from technetium-99m and for beta emitters. Therefore, the NUREG was revised to reflect this distinction.

Location	Subject	Comment
Appendix R	Model Procedure for Area Surveys	• Here is another risk analysis example for the standard of 200 dpm per 100 cm^2 for maximum I-125 removable contamination. The model I chose was a situation where the maximum allowable was on the package, that 50 percent of what was on the package was transferred to a worker's hands, that 50 percent of what was on his hands was transferred to the lips, and everything on the lips was swallowed and that there is a high normal uptake to the thyroid gland. There is the reference for the calculations. The dose to the thyroid is two 1000th of a millirad, the effective dose equivalent 0.000058 millirem EDE. If you look at current radiation detectors that nuclear medicine people have in their labs; a thyroid uptake probe, which is also used as a bioassay probe, has about a one percent efficiency for I-125 and 35 counts per minute background at the I-125 peak, which means that you would be counting 0.2 counts per minute for the 35 count per minute background. You can't do that with any accuracy. Even if you use a liquid scintillation counter, and most nuclear medicine departments don't have that, you're still in trouble. It has a higher efficiency, but a 30 count per minute background is typical. The bottom line here is that the standard is scientifically absurd and is unattainable with present radiation detection instrumentation. • The above argument focuses on dpm at the removal down to 20 dpm per 100 cm^2, that in the guidance is admittedly absurd.

NRC Staff Response: Table I of *Federal Register* Volume 63, Number 222, Page 64134, "Acceptable License Termination Screening Values of Common Radionuclides for Building Surface Contamination" provides screening levels for specific radionuclides. This table does not include radionuclides traditionally used in medicine. We agree that the suggested trigger level documented in Table R.3 of 20 dpm/100 cm^2 set for I-125 and I-129 appears low. This value and other values in the table were chosen to be consistent with the values provided in guidance for release of facilities and equipment (Policy and Guidance Directive FC 83-23). However, consistent with the grouping used in Table R.2, I-125 was moved to be grouped with I-131. Additionally, transuranics and I-129 were deleted from this table, because medical licensees do not normally use transuranics or unsealed I-129.

Table Z.20 Comments Provided by the National Institutes of Health, Dated November and December, 1998.

- (Information recommended to be deleted is shown in ~~strike out~~ and information suggested as replacement and/or addition is shown in **bold**.)

Location	Subject	Comment
Entire Document	Development of NUREG	In addition to our input on the proposed revision to Part 35, enclosed is a critique of NUREG-1556, Vol. 9, "Program-Specific Guidance About Medical Use Licenses." In our opinion this NUREG was developed prematurely, since the Regulation had not yet been finalized. The content of the NUREG does not track with the proposed regulation and, in numerous areas, is not technically competent. The Commission should strongly consider withdrawing the NUREG until a proper job of Rulemaking is accomplished. The NUREG should then be developed with the assistance of stakeholders who have the expertise to advise the NRC how to develop appropriate risk based procedure recommendations.
NRC Staff Response: NRC sought to develop the licensing guidance NUREG concurrently with the proposed regulation in an effort to better serve the regulated community. This method allowed the regulated community to comment on the proposed rule and the proposed licensing guidance simultaneously. Although this method has its drawbacks, NRC believes that the benefits of the method outweigh the drawbacks. Additionally, before the final NUREG was issued, all references to 10 CFR Part 35 were reviewed to ensure that statements made in the NUREG reflected the final regulatory requirements.		

Location	Subject	Comment
Entire Document	Risk Analysis	Thank you for the extension of 34 days to develop additional comments on the 10 CFR Part 35 revision and its associated regulatory guidance, NUREG-1556, Vol. 9. As has been stated in earlier comments out of this office, we believe that the revision of Part 35 is being rushed to completion without having performed the appropriate and essential comprehensive risk analysis of the activities proposed to be regulated. No where is the lack of the appropriate risk based methodology more apparent than in the implementation document, NUREG-1556, Vol. 9. The guidelines, procedures and limits proposed in this document for the most part are NOT risk-based and are, in fact, inconsistent with the regulations of 10 CFR Part 20.
NRC Staff Response: We believe that NUREG-1556, Volume 9, is risk-related and performance-based. NRC recognizes the low risk associated with many licensed activities and the ability of medical licensees to develop safe procedures without direct NRC involvement. Because of this, the guidance in Volume 9 was designed to reduce the amount of detailed information that a licensee is required to submit to NRC for review during the licensing process. The adequacy of the licensee's procedures, implementation of the procedures, and the ability of the licensee through these procedures to meet specific performance indicators, will be evaluated during inspections.		
Section 8	Contents of an Application	Page 8-1, 2nd to last paragraph, change order: Short sentence responses, "NA" or "N" responses to Items 5 through 10... should be changed to "NA, N, or short sentence responses to Items 5 through 10..."
NRC Staff Response: The revision was made accordingly.		

Location	Subject	Comment
Section 8.6	Financial Assurance and Recordkeeping for Decommissioning	• Page 8-8, last paragraph: "where licensed material ~~is~~ **was** used or stored, ~~spills or spread of contamination~~ **any information relevant to spills (e.g., where contamination remains after cleanup procedures or when there is reasonable likelihood that contaminants may have spread)** and leaking sealed sources ~~(see Figure 8.2)~~. • Delete reference to/and Figure 8.2. Figure 8.2 has no relevancy. • Page 8-9: The regulations given in 10 CFR 30.35 are very clear; much more so than the paraphrased comments on page 8-9. The requirements for financial assurance for unsealed vs sealed sources should be more clearly identified in this guide. Suggestion to add the following: "Most medical use applicants and licensees do not need to take action to comply with the financial assurance requirements because: a. either their total inventory of unsealed licensed material does not exceed the limits in 10 CFR 30.35 **(10E5 times the applicable quantities set forth in appendix B)**, or the half life of the unsealed byproduct material used does not exceed 120 days; or b. **If the total inventory of sealed sources does not exceed the limits in 10 CFR 30.35 (10E10 times the applicable quantities of appendix B). Examples are shown in Table 8.2.**

NRC Staff Response: The following response is provided in corresponding bullets to the comments.

- Revised to: "Even if no financial assurance is required, licensees are required under 10 CFR 30.35(g), to maintain records important to decommissioning in an identified location (see Figure 8.2). These records must, in part, identify all areas where licensed material is (or was) used or stored and any information relevant to spills (e.g., where contamination remains after cleanup procedures or when there is reasonable likelihood that contaminants may have spread) and leaking sealed sources."
- Figure 8.2 is relevant because it illustrates recordkeeping for compliance with 10 CFR 30.35(g).
- The existing wording provides accurate guidance for compliance with 10 CFR 30.35 and clearly states why most medical applicants and licensees need not take any action to comply with 10 CFR 30.35. Therefore, no revision is necessary.

Location	Subject	Comment
Section 8.6	Financial Assurance and Recordkeeping for Decommissioning	• Table headings in 10 CFR 30, Appendix B are incorrect. • Page 8-10, 2nd paragraph: Table 8.2 is not all-inclusive without the changes indicated below; the licensee may be led to believe that the authorization is only for the three radionuclides listed in table 8.2. Recommended change: "NRC will authorize **sealed source** possession exceeding the limits **given in 10 Part 30.35 (d)** ~~shown in Table 8.2~~ without requiring decommissioning financial assurance, for the purpose of normal sealed source exchange for no more than 30 days. **Examples are shown in Table 8.2.**"
NRC Staff Response: • The table headings in Appendix B to 10 CFR 30 (i.e., "Material" and "Microcuries") are correct. The relation between the comment and the NUREG is unclear. • Revised to: "NRC will authorize sealed source possession exceeding the limits given in 10 Part 30.35(d) without requiring decommissioning financial assurance, for the purpose of normal sealed source exchange for no more than 30 days. Table 8.2 shows examples of the limits for select sealed sources."		
Section 8.8	Purpose(s) for Which Licensed Material Will Be Used	Pages 8-14 to 8-19: These pages describe methods of therapy treatments, in unnecessarily excessive detail. These descriptions are available in the literature and in textbooks, and need not be included in this Regulatory Guide.
NRC Staff Response: The section was revised to remove textbook information.		

Location	Subject	Comment
Section 8.10	Radiation Safety Officer	• The training requirements are subject to change based on changes in Part 35, and a radiation safety exam is not necessary for the RSO; a description of training and experience is sufficient. • Page 8-23, 3rd bullet: "...AND ... Written certification, signed by a preceptor RSO, that the above training and experience has been satisfactorily completed." This is unnecessary given the professional and experience qualifications of health physicists. This is also asking for a contract between a preceptor RSO and the NRC, which may put a preceptor at potential risk should unforseen circumstances arise. • Page 8-23, 6th bullet: "Descriptions of training and experience will be reviewed using the criteria listed above. This documentation will be reviewed on a case-by-case basis to determine whether the applicable criteria in Subparts B or J are met." Review on a "case-by-case" basis is not only too discretionary, but it will be extremely time consuming for the NRC to review each case, and then to defer to ACMUI if necessary. This may cause unacceptable delays in the assignment of AUs. The NRC should rely on the licensee's internal review system, which is always available for NRC review.

NRC Staff Response:

- The final NUREG was revised to reflect the requirements in the final regulation.
- Preceptor certification is a requirement of 10 CFR Part 35. The language chosen reflects the language used in the regulation.
- NRC review of training and experience is not too discretionary. The review is initially performed by comparison with the applicable requirements found in Subpart B. If the requested individual does not meet the training requirements provided for in the regulations, the license reviewer may request additional information from the licensee or may, in rare cases, refer the training and experience to the ACMUI for review. Referrals to the ACMUI are normally made for new types of medical use not previously described in the regulations or guidance. This distinction was added to this section.

Location	Subject	Comment
Section 8.11	Authorized Users	• Pages 8-23 through 8-25: The training requirements are subject to change based on changes in Part 35, and a radiation safety exam is not necessary. The NRC's views on the duties of an AU are unclear; the training requirements are not always going to be commensurate with these duties, i.e., for in vitro and animal research, calibration of survey instruments, and other uses that do not involve the intentional exposure of humans. • Must the licensee "notify the NRC within 30 days if an AU permanently discontinues his/her duties..." for AUs who do not use byproduct material for human use? Would it not be sufficient for the licensee to keep an updated file which is subject to NRC review?
NRC Staff Response: • The final NUREG was revised to reflect the requirements in the final regulation. Responsibilities of authorized users are clearly listed in the discussion part of this section. • With regard to authorized users, the notification requirements in 10 CFR 35.14 apply only to authorized users involved in medical use.		

Location	Subject	Comment
Section 8.11	Authorized Users	Page 8-25, 7th bullet of page: "Descriptions of training and experience will be reviewed using the criteria listed above. This documentation will be reviewed on a case-by-case basis to determine whether the applicable criteria in 10 CFR Part 35 are met. If the training and experience do not appear to meet...the NRC may request the assistance of its ACMUI." Review on a "case-by-case" basis is not only too discretionary, but it will be extremely time consuming for the NRC to review each case, and then to defer to ACMUI if necessary. This may cause unacceptable delays in the assignment of AUs. The NRC should rely on the licensee's internal review system, which is always available to the NRC for review.
NRC Staff Response: NRC review of training and experience is not too discretionary. The review is initially performed by comparison with the applicable requirements found in 10 CFR Part 35. If the requested individual does not meet the training requirements provided for in the regulations, the license reviewer may request additional information from the licensee or may, in rare cases, refer the training and experience to the ACMUI for review. Referrals to the ACMUI are normally made for new types of medical use not previously described in the regulations or guidance. This distinction was added to this section.		
Sections 8.12, 8.13, and 8.14	Training Requirements	Training requirements are subject to change based on changes in Part 35. Radiation safety exam is not necessary.
NRC Staff Response: The final NUREG was revised to reflect the requirements in the final regulation.		

Location	Subject	Comment
Section 8.18	Dose Calibrator and Other Dosage Measuring Equipment	• Page 8-40, 2nd paragraph: "Currently no alpha emitting nuclides are used in unsealed form in medicine. Therefore guidance is not provided in this document on the measurement of these radionuclides." Research involving alpha-labeled monoclonal antibodies for cancer therapy is rapidly progressing, and it is likely that use of this technique will occur in the near future. The authors of this guide should consider addressing model procedures for alpha measurement, i.e., emerging technology. • Page 8-40, 3rd paragraph: "Equipment used to measure dosages that emit gamma~~, alpha, or~~ **and** beta radiation must be calibrated for the applicable radionuclide being measured (per the above NUREG discussion regarding alpha emitters).
NRC Staff Response: NRC believes that it is best to provide guidance on alpha-labeled monoclonal antibody measurement when the research results in more wide-spread use. In accordance with 10 CFR 35.60, all instruments used to measure byproduct material (including alpha emitters) must be calibrated. Therefore, no revision appears necessary in response to the second comment.		
Section 8.19	Dosimetry Equipment – Calibration and Use	Page 8-41, 3rd paragraph, Discussion: "The applicant must possess a calibrated dosimetry system...to perform calibration measurements of sealed sources **to be used for patient therapy**." (Sealed sources are used for many procedures – as markers, irradiators, etc. This guide must indicate that this ITEM 9 refers to sealed sources used for therapy.)
NRC Staff Response: NRC agrees with the proposed revision and added "to be used for patient therapy."		

Location	Subject	Comment
Section 8.21	Radiation Protection Program	• Page 8-46 "Additionally, any calculations or measurements used to demonstrate compliance with NRC regulation must be representative of typical quantities in use or maximum patient doses." Unclear as to which this sentence requires. Which does the NRC really want, representative of typical quantities in use or maximum patient doses – is it one or the other at the licensee's discretion? • Page 8-46, under bulleted item: "Material Receipt and Accountability" – should include only "Ordering and Receiving" through "Use" records bullets. The remaining items: Patient or Human Research Subject Release, Safety Procedures for Therapy Treatments..., Safety and Device Calibration Procedures, Administration Requiring a Written Directive, Safe Use of Unsealed Licensed Material, Maintenance of Therapy Devices Containing Sealed Sources, Spill Procedures, Emergency Response for Sealed Sources..., should be placed under different headings. For example, change "Minimization of Contamination" to "Minimization of Exposure and Contamination," and include "Area Surveys," "Spill Procedures," "Leak Tests," and "Safe Use of Unsealed Licensed Material." "Emergency Response for Sealed Sources or Devices..." should be included under "Operating and Emergency Procedures." Also, add a heading, "Patient Use," under which the following should be included: "Administrations Requiring a Written Directive," "Patient or Human Research Subject Release," and "Safety Procedures for Therapy Treatments Where Patients are Hospitalized." Add heading "Equipment Performance," under which "Maintenance of Therapy Devices Containing Sealed Sources" and "Safety and Device Calibration Procedures" are included.

NRC Staff Response:

- The referenced sentence was deleted.
- The items "Ordering and Receiving" through "Use Records" were subset under "Material Receipt and Accountability." The additional changes were not made, because many of the remaining items are part of the radiation protection program and require development of various "Operating and Emergency Procedures."

Location	Subject	Comment
Section 8.23	Occupational Dose	Page 8-50, 1st paragraph: "If external dose monitoring is necessary, the applicant should describe the type of personnel dosimetry~~, i.e., film badges or thermoluminescent dosimeters (TLDs)~~, that will be used~~ by personnel~~." **Whole body dosimeters may be composed of film, thermoluminescent (TLD), or optically stimulated luminescence (OSL) detectors. Extremity (ring) dosimeters may be composed of TLD or OSL detectors.** Also, the second half of this paragraph is redundant and therefore should be omitted: ~~"if occupational workers handle licensed material, the licensee should evaluate the need to provide extremity monitors [ie., required if likely to receive a dose in ...] in addition to whole body badges."~~
NRC Staff Response: The first sentence was revised to include OSL dosimeters. The remainder of the paragraph is not redundant because it: (1) discusses the licensee's responsibility to evaluate the need to provide extremity monitoring; and (2) provides guidance on where dosimeters should be worn.		

Location	Subject	Comment
Section 8.24	Public Dose	• Perhaps NUREG-1556 could provide more guidance on "security" of radioactive material; reference "EGM 98-004." • Page 8-52, under "Discussion": "...Public dose is controlled, in part, by ensuring that licensed material is secured ~~(e.g., located in a locked area)~~ to prevent unauthorized access or use." Licensees should be able to use their own discretion as to how they will secure from unauthorized access.
NRC Staff Response: • It is inappropriate for the NUREG to discuss specific NRC Enforcement Policies. As a general overview, the applicant was referred to NUREG-1600, "General Statement of Policy and Procedures on NRC Enforcement Actions," in Section 8.22. • NRC agrees that licensees should be able to use their own discretion as to how licensed material will be secured from unauthorized access. Therefore, an example of how licensed material may be secured was given rather than prescribing a single acceptable method.		
Section 8.24	Public Dose	• Page 8-53, 2nd paragraph: "Licensees can determine the radiation levels adjacent to licensed material either by **direct measurement,** calculations, or a combination of direct measurements and calculations using some or all of the following..." • Page 8-53, 4th paragraph: "...During NRC inspections, licensees must be able to provide documentation demonstrating, by measurement or calculation**, or both,** that the total effective dose equivalent to the individual likely to receive the..."
NRC Staff Response: • The proposed revision to paragraph 2, Page 8-53, was made accordingly. • The proposed revision to add "or both" was made in paragraph 4, page 8-53.		
Section 8.25	Minimization of Contamination	Reference Regulatory Guide 8.23 "Radiation Safety Surveys at Medical Institutions," which provides comments on acceptable fixed and loose contamination limits.
NRC Staff Response: Tables R.2 and R.3 of Appendix R were referenced in this section.		

Location	Subject	Comment
Section 8.26	Operating and Emergency Procedures	• References to 10 CFR 35 are not consistent with the numbering in Part 35. • Page 8-54, 3rd bullet: Add the words "written directive." "Instructions for administering licensed material in accordance with the **written directive** (WD)." • Page 8-55, under Discussion: "Applicants shall develop operating and emergency procedures that minimize radiation ~~safety risks, while keeping radiation exposures ALARA."~~ **exposure consistent with the ALARA principle.**"
NRC Staff Response: • The final NUREG was revised to reflect the appropriate references from the final regulation. • Abbreviations are found on page xvii. Written Directive was previously abbreviated in Section 1.3. • To keep the sentence consistent with 10 CFR 20.1101, it was changed to: "Applicants shall develop, document, and implement specific procedures as part of a radiation protection program (e.g., operating and emergency procedures) based on sound radiation protection principles to achieve occupational doses and doses to members of the public that are ALARA."		
Section 8.26	Operating and Emergency Procedures	• Page 8-55, 3rd sentence in 3rd paragraph under "Discussion:" "...The change in emphasis when an operation or autopsy is to be performed is due to the possible exposure of the hands and face to relatively intense beta radiation (if present) **in addition to the gamma component**. • Page 8-56, 1st paragraph: "The NRC must be notified when licensed material in excess of 10 times the quantity specified in Appendix C to part 20 is **discovered to be** lost or stolen."
NRC Staff Response: • The revision is unnecessary because the existing text states, "possible exposure to...beta radiation." Since gamma rays are mentioned in the second sentence of the existing text, it would be redundant to mention it when discussing an operation or autopsy. • The phrase "after its occurrence becomes known to the licensee" was added.		

Location	Subject	Comment
Sections 8.27 - 8.34 and Appendix Q	Various Sections	References to Part 35 are incorrect.
NRC Staff Response: The final NUREG was revised to reflect the appropriate references from the final regulation.		
Section 8.28	Ordering and Receiving	NUREG-1556 should include a statement that if the licensee ships radioactive material from their facility, that the licensee must ensure that the receiver has a license to receive the material.
NRC Staff Response: The proposed revision refers to transfer, yet Section 8.28 deals with ordering and receiving exclusively. Therefore, the revision is inappropriate. Section 8.44, "Waste Management," includes a reminder that licensees verify that the waste recipient is properly authorized to receive the material prior to transfer.		
Section 8.33	Area Surveys	• Page 8.62: A survey of the patient's bed linens is suggested. The NRC should also suggest that a survey of all trash exiting the patient's room be surveyed. • If the new proposed Part 35 is only going to require a semi-annual inventory of sealed sources, then this guide should be revised to only require a semi-annual survey of sealed source storage areas instead of quarterly surveys. • The section regarding Contamination Surveys should reference Regulatory Guide 8.23 "Radiation Surveys at Medical Institutions."
NRC Staff Response: • The proposed revision was made. • The final NUREG was revised to reflect the requirements in the final regulation. • As indicated in the references, Regulatory Guide 8.23 was used in formulation of this NUREG.		

Location	Subject	Comment
Section 8.44	Waste Management	• Page 8-81: 49 CFR should be included in the list of referenced regulations at the beginning of this section. • Page 8-82, 2nd bullet, 1st item: It should be clarified that only excreta from patients is exempt, not fluids. Blood is not exempt.
NRC Staff Response: • 10 CFR 71.5 requires compliance with 49 CFR. Therefore, a reference to 49 CFR is not needed. • The existing text makes no reference to patient fluids. The existing text references "excreta from patients." Since "fluids" are not referenced and blood is not excreted from patients, the proposed revision is unnecessary.		

Location	Subject	Comment
Appendix F	Typical Duties and Responsibilities of the Radiation Safety Officer and Sample Delegation Authority	• Page F-2: Model Delegation of Authority: The requirement for signatures of the Management Representative and the RSO should be deleted. The position of RSO is a professional one, and the duties and responsibilities of ensuring the safe use of radiation is inherent in this occupation. The successful performance of the Radiation Safety Program and of the RSO is constantly reviewed by the NRC via inspections, license applications, and informal communications; the request for a contractual signature is unwarranted. • In addition, the following: "It is estimated that you will spend _____ hours per week conducting radiation protection activities" must be removed. What is the purpose of contracting a time commitment? Successful completion of 10 CFR 35 requirements should be the criteria used for judging a successful radiation safety program; the amount of time spent doing so is irrelevant.
NRC Staff Response: • 10 CFR 35.24 requires the RSO's agreement in writing to be responsible for implementing the radiation protection program. 10 CFR 35.24 also requires that the licensee establish, in writing, the RSO's authority, duties, and responsibilities. • Appendix F is a model procedure. The model procedures provide acceptable procedures for the RSO's duties and responsibilities, and a sample delegation of authority. Licensees may either adopt the model procedures or develop their own procedures to meet the requirements. NRC believes that management and the RSO should come to a mutual understanding of the approximate time required to perform the RSO functions. Otherwise, an individual, such as a physician authorized user, may be appointed RSO, but may not have sufficient time away from his or her regular physician duties to accomplish the RSO functions.		
Appendices G and H	Various Appendices	Subject to change in accordance with final 10 CFR 35 document.
NRC Staff Response: The final NUREG was revised to reflect the requirements from the final regulation.		

Location	Subject	Comment
Appendix J	Model Procedures for Dose Calibrator Calibration	• Page J-1, 1st paragraph: "We will consider repair, replacement, or arithmetic correction**, as applicable,** if the dose calibrator falls outside the suggested tolerances." • "After repair, adjustment, or **a** relocation to another building **which is likely to affect performance** of the dose calibrator, we will repeat the above tests before use" • Page J-1, middle of the page: "We will assay at least one relatively long-lived source such as Cs-137, Co-60~~, cobalt 57 (~~Co-57, or ~~radium 226 (~~Ra-226)." • Page J-2: Add to list and to list on J-6 under accuracy: **"A sticker will be affixed to the dose calibrator to indicate the dates of the linearity (and accuracy) checks."** • Page J-5: Delete from NUREG-1556 all references that say "Subtract background from the indicated activity to obtain the net activity," and simply state to **"measure background and record the net activity."**

NRC Staff Response:

- This sentence was deleted and the note describing the regulatory requirements was inserted instead.
- The proposed revision results in ambiguity in terms of what is likely to affect performance of the dose calibrator. Therefore, no revision was made.
- The proposed revision deletes the meaning of two abbreviations. Since this is the first time in this document that Co-57 and Ra-226 have been abbreviated, the full terms are needed here.
- The proposed revision does not appear to add value, because a record of the test is required. Therefore, the revision is unnecessary.
- The phrase "subtract background from the indicated activity to obtain the net activity" has been deleted from this appendix.

Location	Subject	Comment
Appendix L	Model Procedures for an Occupational Dose Program	• Page L-1: Add a paragraph before ALARA, entitled, Occupational Dose Limits, and add some definitions and explanations. For example: – The occupational dose limits for adults is given in 10 CFR 20.1201: (1) Annual limit, which is the more limiting of: (i) The total effective dose equivalent (TEDE or H_E) being equal to 5 rem (0.05 Sv). The TEDE is the sum of the deep dose equivalent (DDE or H_d) from penetrating external radiation, and the committed effective dose equivalent (CEDE or $H_{E,50}$) from internal radiation exposure. Or, (ii) the sum of the deep dose equivalent and the committed dose equivalent (CDE or $H_{T,50}$) to any individual organ or tissue other than the lens of the eye being equal to 50 rem (0.05 Sv). And (2) The annual limits to the lens of the eye, to the skin, and to the extremities, which are: (i) An eye dose equivalent of 15 rems (0.15 Sv), and (ii) A shallow-dose equivalent (H_S) of 50 rems (0.50 Sv) to the skin or to any extremity. – The deep dose equivalent is the dose received from external penetrating radiation at a point on the whole body located at a tissue depth 1000 mg/cm^2 (1 cm) below the skin surface. – The shallow dose equivalent is the dose received averaged over a 1 cm^2 area, located 7 mg/cm^2 (0.0007cm) below the skin surface. – The CDE ($H_{T,50}$) is the cumulative dose received by an organ that will be received from an intake of radioactive material during the 50-year period following the intake. – The CEDE is the sum of the CDE to each individual organ multiplied by the organ weighting factor. CEDE = _ $[H_{T,50}w_T]$
NRC Staff Response: The suggested definitions for dose limits appears unwarranted. A reference to the definitions in 10 CFR 20.1003 was added to this appendix.		

Location	Subject	Comment
Appendix L	Model Procedures for an Occupational Dose Program	• Page L-1: Edit the 1st paragraph by placing the 1st sentence under "External dose Exposure" prior to the 1st sentence of the 1st paragraph, i.e., **"The mechanism by which doses to individuals from exposure to radiation is evaluated is called dosimetry. Dosimetry is required for individuals likely to receive in 1 year a dose in excess of 10% of the applicable..."** • Page L-1, 3rd paragraph under "External Dose exposure": Add: "There are three **occupational** dose limits included in..." • Page L-2, 1st paragraph, add: "...(i.e., adult, minor, or **the fetus of a** declared pregnant woman)." • Page L-2, 1st bullet: add: "For adults **occupational workers** who are likely to receive an annual dose in excess of any of the following..." • Delete the bulleted information on Page L-2 which enumerates 10% of each limit. It is sufficient to say that **"monitoring devices for external dose is required when an occupational worker or minors are to receive 10% of the applicable limits**." The individual numbers representing 1/10th of these values need not be listed. • Page L-3: 1st paragraph: "External dose is determined by using individual monitoring devices such as film ~~badges~~ **or optically stimulated luminescence (OSL) badges**, or thermolurninescent dosimeters ~~(DDE)~~ **TLD's**."

NRC Staff Response:

- We agree with the proposed revision.
- The proposed revision to the third paragraph on page L-1 is unwarranted because the Appendix is titled, "Model Procedures for an Occupational Dose Program."
- We agree with the proposed revision.
- The proposed revision to the first bullet on page L-2 is unwarranted because the Appendix is titled, "Model Procedures for an Occupational Dose Program."
- The individual numbers representing one-tenth of the limits are provided for ease of reference.
- The following revision was made: "External dose is determined by using individual monitoring devices such as film badges, optically stimulated luminescence dosimeters (OSL), or thermolurninescent dosimeters (TLDs)."

Location	Subject	Comment
Appendix L	Model Procedures for an Occupational Dose Program	Delete Page L-3, 6th paragraph: ~~"If the licensee determines that extremity monitoring is required, it may be appropriate to use an extremity dosimeter for some, but not all, radiation exposure. The licensee could supply an extremity dosimeter when exposure is non-uniform. When exposure is uniform, the shallow dose equivalent measured by a torso dosimeter would be representative of the shallow dose equivalent to the extremities, and separate extremity monitoring would not be needed."~~ Add: **Extremity dosimeters are required when the extremities are likely to receive 10% of the applicable limit.** This 6th paragraph is very confusing. If the exposure is uniform, then the 5 rem to the whole body is the limiting dose; extremity monitoring is therefore of no concern because the extremity limit is 10 times the whole body dose. Radiation fields are never static or uniform over the entire body when radioactive material is handled; exposure to the hands is always higher because of distance and/or torso shielding (i.e., beta shields or leaded shields) factors. NUREG- 1556 should simply state that extremity dosimeters are required when the extremities are likely to receive 10% of the applicable limit. This information can determined by using historical extremity dosimetry data, or by considering the radionuclide used and expected amount of time it will be handled yearly.
NRC Staff Response: The sixth paragraph of page L-3 was deleted. The proposed revision was not added because this issue was already addressed in the appendix.		

Location	Subject	Comment
Appendix L	Model Procedures for an Occupational Dose Program	• Page L-4 Investigation Levels – External Dose Monitoring: The presentation of investigation levels does not reflect updated version of yearly dose limits in 10 CFR 20. Why are the Investigation Levels in terms of dose per quarter; this is inconsistent with the updated dose limits which are based on a yearly, not quarterly period. Why are the lens of eyes combined with the whole body, head and trunk, active blood forming organs, or gonads, and why are the extremity and skin of the whole body investigational levels different when their dose limits are the same? Why is there not a separate investigation for lens of the eyes? Also, why not just state "whole body," the "head and trunk, active blood forming organs, or gonads" are implied by this definition; similarly for the "hands and forearms, feet and ankles which are defined as "extremities." • The dose thresholds per quarter which would require investigation, according to this section, are much too conservative. The Investigation Level I per quarter for the whole body (etc.) is only 2% of the annual limit, the "hands and forearms, feet and ankles" is 3.7%, and "the skin of the whole body" is 1.5% of the annual limits. For the whole body, this means that an investigation must be performed for an average dose of 42 mrem per month! Additionally, personnel who will not receive 500 mrem in a year, and who are therefore not monitored, may reach 125 mrem in a quarter. The preferred investigation action guideline would be a threshold of a certain reasonable percentage of the yearly annual dose. For example, **"Investigation Level I when occupational dose reaches 10% of the annual limit, and Investigational Level 2 at 30%."**
NRC Staff Response: • Table L.1 is part of a model procedure and, therefore, not required. The model procedures provide acceptable procedures for an occupational dose program. Licensees may either adopt the model procedures or develop their own procedures to meet the requirements. Nonetheless, Table L.1 was revised to be consistent with 10 CFR Part 20 dose limits (e.g., the skin and extremity investigational levels are the same, etc.). • We agree with the proposed revision.		

Location	Subject	Comment
Appendix L	Model Procedures for an Occupational Dose Program	• Page L-6 Internal Dose exposure: This section is poorly constructed, and does not include clear and concise information regarding the definitions and use of ALIs and DACs. • Page L-6, 1st paragraph: "With respect to internal exposure, you are required to monitor ~~your~~ occupational intake of radioactive material and assess the resulting dose if it appears likely that you will to receive greater than 10% of the ALI from intakes in 1 year..." • Page L-6: Switch paragraphs 2 and 3, and other additions/deletions throughout the page: "For each class of each radionuclide, there are two **Annual Limit on Intakes (**ALIs), one for ingestion and one for inhalation. The ALI **(μCi)** is that quantity of radioactive material that, if taken into the body of an adult worker **over the course of a year** by the corresponding route would result in a committed effective dose equivalent (CEDE) of 5 rems (0.05 Sv) **(known as the "SALI" - "S"for stochastic),** or a committed dose equivalent of 50 rems **(known as the "NALI" - "N" for non-stochastic)**..."

NRC Staff Response:

- Much of this section has been revised. For instance, the text regarding how to operate a bioassay program, pages L-7 to L-20, was deleted. The detailed procedures were replaced with a referral to the appropriate Regulatory Guides and NUREG that cover this subject in greater detail.
- We agree with the proposed revision.
- The suggested changes to page L-6 do not appear to add much value to the guidance. Therefore, no revision was made in response to these suggestions.

Location	Subject	Comment
Appendix L	Model Procedures for an Occupational Dose Program	• Page L-6, paragraph 3: "~~Exposure to airborne radioactivity at a level of 1 DAC for 1 year...)~~ **The Derived Air Concentration (DAC) for each class of radionuclide is the concentration of airborne radioactivity (μCi/ml) that, if an occupational worker were to be continuously exposed for 2000 hours (1 year), would result in a committed effective dose equivalent of 5 rems (0.05 Sv), or a committed dose equivalent of 50 rems (0.5 Sv)** to any individual organ or tissue, again, with no..." **The ALI and DAC for each radionuclide in a specific chemical form is listed in 10 CFR Part 20, Appendix B.** • Page L-6, 5th paragraph: "The **total** effective dose equivalent (TEDE) concept ~~described above~~ makes it possible to combine both the internal and external doses in assessing the overall risk to the health of an individual. The 10 CFR 20 ~~dose methodology evaluates the doses to all major body organs~~ **ALI and DAC numbers** reflect the doses to all principal organs that are irradiated**, and will indicate the committed effective dose equivalent (via the SALI) or the committed dose equivalent to an individual organ (via the NALI) due to an intake of a particular radionuclide compound. The ALI and DAC were derived by multiplying a unit intake by the appropriate organ weighting factors W_T, for the organs specifically targeted by the radionuclide compound,** and then summing the organ-weighted doses to obtain a whole body risk-weighted "effective dose." **Per 10 CFR 20 Appendix B, when an ALI is defined by the stochastic dose limit, this value alone, is given. When the ALI is determined by the non-stochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parentheses.**
NRC Staff Response: The proposed revisions, with minor changes, were incorporated.		

Location	Subject	Comment
Appendix L	Model Procedures for an Occupational Dose Program	Page L-6, Add: **If the intake consists of a mixture of radionuclides, then: [ALI/Intake] < 1.** Suggestion, give examples: Total effective dose equivalent: If the dose is external only, then TEDE = deep dose equivalent for whole body. If the doses are internal only, then: 1) Ingestion: TEDE (Intake/ALI) x 5 rem; 2) Inhalation: TEDE (Concentration/DAC) (Number of hours exposed)/ 2000 hours) x 5 rem. If the doses are internal and external: TEDE = [deep dose equivalent] + [(Intake/ALI) x 5 rem] + [(Concentration/DAC) (Number of hours exposed)/ 2000 hours) x 5 rem].
NRC Staff Response: The suggested addition to sum external and internal doses, excluding the examples, was included in a separate section titled "Summation of External and Internal Doses."		

Location	Subject	Comment
Appendix M	Guidance for Demonstrating that Individual Members of the Public will not Receive Doses Exceeding the Allowable Limits	The step-by-step tabulated example of calculation method for determining that allowable limits are met, Pages M-5 - M-7 are excessive, and quite confusing. Table M.2 can be replaced by simplifying the example. An abbreviated (prototype) suggestion is given below: • Step 1: Consider distance from unshielded source only. Using the inverse square law: $I_2d_2^2 = I_1d_1^2$, $1_2 = I_1d_1^2/d_2^2$. (Define terms...). I_1 = 5000 mrem/hr (3.28 ft)^2 / (15 ft)^2 = 239 mrem/hr. Yearly dose = 239 mrem/hr x 24 hrs/day x 365 days/year = 2.09x10^6 mrem/year. • Step 2: Include Occupancy Factor: "~~Joe~~ Reviews ~~his~~ assumptions **and make a realistic estimate**, ~~recognizes~~ **by considering** that the~~ secretary is not at the desk~~ **chair and desk are not occupied 24 hours/day; recalculate the annual dose using an occupancy factor**; ~~he decides to make a realistic estimate of the number of hours the secretary sits in the chair at the desk,~~ keeping his other assumptions constant... Yearly dose = [Dose rate at the location] x [occupancy factor], Yearly dose = [239 mrem/hr] x [(5 hours/day)(3 days/week)(52 weeks/year)] = 1.86x10^5 mrem/year. • Step 3: Include Source Use Factor. Yearly dose = [Dose rate at the location] x [occupancy factor] x [Fraction of time the source is exposed], [Fraction of time source exposed] = Max exposure time per patient x number of patients per day], [Fraction of time source exposed] = {1 minute x 16 patients per day}/1440 minutes per day}, [Fraction of time source exposed] = 0.011, Yearly dose = [Dose rate at the location] x [occupancy factor] x [Fraction of time the source is exposed], Yearly dose = 1.86 x 10^5 mrem/year x 0.011 = 2046 mrem/yr. • Step 4: Include shielding. $I = I_oe^{-ux}$ (Define terms) etc.
NRC Staff Response: The proposed revisions delete specific instructions that could result in confusion. Furthermore, the existing guidance appears accurate and easy to follow. Therefore, the proposed revision is unnecessary.		

Location	Subject	Comment
Appendix N	Emergency Procedures	• Appendix N should distinguish between spills in restricted and unrestricted areas. This guide should also reference Regulatory Guide 8.23 "Radiation Safety Surveys at Medical Institutions." • Minor spills of Liquids and Solids. Changes: – No comment – Prevent the spread of contamination by covering the spill with **"cram"- labeled** absorbent paper. **Carefully identify the boundaries of the spill.** – **Wearing gloves and protective clothing such as a lab coat and booties,** clean up the spill using ~~disposable gloves and~~ absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a **"cram"- labeled** bag for transfer... – Survey the area with a ~~low-range~~ radiation ~~detector~~ survey meter **sufficiently sensitive to detect the radionuclide.** – **Smear the area to ensure contamination is below limits.**

NRC Staff Response:

- The guidelines for responding to spills may be used for spills both in restricted and unrestricted areas. As discussed previously, Regulatory Guide 8.23 was used in development of this NUREG (see the Abstract).
- The proposed revision, "Prevent the spread of contamination by covering the spill with 'cram'-labeled absorbent paper. Carefully identify the boundaries of the spill." is unnecessary because the absorbent paper is typically used to blot the spill and is promptly disposed of as radioactive waste. Therefore, labeling absorbent paper that is used quickly and then disposed of is unnecessary. Also, the boundaries of the spill will not necessarily be known until the survey (see Step 4) is performed.
- We agree with the proposed revision, "Wearing gloves and protective clothing such as a lab coat and booties, clean up the spill using absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a caution radioactive material-labeled bag for transfer..."
- The following revision was made to the last two bullets: "Survey the area with a low-range radiation detector survey instrument sufficiently sensitive to detect the radionuclide. Smear the area to ensure contamination is below trigger levels..."

Location	Subject	Comment
Appendix N	Emergency Procedures	• Minor spills of Liquids and Solids. Changes, cont.: – **Additional decontamination efforts may be required to achieve acceptable levels listed in Regulatory Guide 8.23 "Radiation Safety Surveys at Medical Institutions."** – ~~Report the incident to the RSO.~~ The RSO does not need to be informed of minor spills, unless it involves skin contamination or the spill occurred in an unrestricted area. This requirement as to whether or not to involve the RSO for a minor spill should be at the discretion of the RSO whom should also be permitted to delegate responsibility to staff. • Major Spills of Liquids and Solids. Changes: – Clear the area. Notify all persons not involved in the spill to vacate the room **after they have monitored their shoes**. – Prevent the spread of contamination by covering the spill with **cram-labeled** absorbent paper, but do not attempt to clean it up. To prevent the spread of contamination, **clearly indicate the boundaries of the spill, and** limit the movement of all personnel who may be contaminated.

NRC Staff Response:

- As discussed previously, Regulatory Guide 8.23 was used to prepare this document (see Abstract).
- RSO notification of minor spills provides a means for the RSO to become aware of potentially unsafe practices or procedures that need refinement. Therefore, no revision was made.
- If an individual was not involved with the spill, there is no need for the individual to monitor his/her shoes before leaving the room. Therefore, no change was made.
- We agree with the proposed revision to major spills, except if an individual was not involved with (or near) the spill, there may not be a need for the individual to monitor his/her shoes before leaving the room.

Location	Subject	Comment
Appendix N	Emergency Procedures	• Major Spills of Liquids and Solids. Changes, cont.: – ~~Shield the source if possible. Do this only if it can be done without further contamination or a significant increase in radiation exposure.~~ Shielding the source is extremely impractical, and most probably unnecessary. – ~~Close the room and lock or otherwise~~ secure the area to prevent entry. – Notify the RSO immediately. – "...~~if contamination remains, induce perspiration by covering the area with plastic~~....." For skin contamination it is not good to induce perspiration by covering the area. This could lead to absorption through the pores and an internal intake. It is better to decontaminate the area until no more contamination can be removed, or until skin becomes irritated. Take measurements with meter and calculate the skin dose in the worst case scenario; if the dose is less than 10% of the annual limit, then it is best to leave it alone.

NRC Staff Response:

- Shielding the source may be practical in some situations when the exposure rate is excessive; therefore, we have retained this item.
- The deletion of the phrase "close the room and lock" was not accepted, because this phrase includes an example of securing the contaminated area.
- Add the caveat that the RSO should consider inducing perspiration (instead of washing the skin to the point of irritation, because this increases blood flow to the skin surface resulting in an increased potential for intake).

Location	Subject	Comment
Appendix N	Emergency Procedures	• Page N-2, 1st paragraph: "For some spills of short-lived radionuclides, the best spill procedure may be restricted access pending complete decay." This advice is very misleading as written. Per 10 CFR 30.50 (b), twenty four hour report to the NRC is required for: 1) an unplanned contamination that: (i) Requires access to the contaminated area...to be restricted for more than 24 hours by imposing... or by prohibiting entry into the area; (ii) Involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B...; (iii) Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination...." Change this sentence to: "For some spills of radionuclides **with half-lives shorter than 24 hours, in amounts less than five times the lowest ALI, an alternative** spill procedure may be to restrict access pending complete decay." • Page N-2, Table N-1, Relative Hazards of Common Radionuclides: What is the basis upon which the quantities in this table were determined to distinguish between major vs. minor spills? • Page N-2, Spill Kit: This type of detail is unnecessary. Enumeration of number of items is unnecessary. If the licensee states in their application that they will adopt the precautions outlined in Appendix N, Spill Kit, the licensee should not be held to requiring exactly 6 pairs of gloves, 2 lab coats, etc. The list is incomplete; urine bioassay cups, for example, are also important to have.

NRC Staff Response:

- We agree with the proposed revision.
- The precursor to Table N.1 was Table J-1 found in Regulatory Guide 10.8, Revision 2. Table J-1 was based in part on NCRP Report No. 30, "Safe Handling of Radioactive Materials."
- The list was modified to be more generic, consistent with the list provided in Volume 11 of this NUREG series, "Program-Specific Guidance About Licenses of Broad Scope."

Location	Subject	Comment
Appendix N	Emergency Procedures	• Pages N-3, Item 2 and N-4, Item 3: NRC does not need to give guidance to prevent possible splashing of "foreign materials." Change: "The surgeon and the personnel involved in the surgical procedures will wear protective gear for ~~the~~ **eye** protection ~~of the eye~~ from possible splashing of ~~foreign materials, as well as from beta radiation~~ **radioactive material**." • Page N-4, Item #4 under "Autopsy of Patients Who Have Received Therapeutic Amounts of Radionuclides" should not be so specific. The NRC has no right to dictate how a pathologist performs an autopsy. Certainly removing an entire block of tissue containing the nuclide would limit the radiation exposure, but the NRC does not have to be that detailed. • The RSO should not have to be informed of any hazard associated with Emergency Surgery or an Autopsy. The RSO should determine the criteria in which he/she is to be notified and the NRC should not dictate when the RSO be notified of a situation. Let the RSO manage the program as he/she deems appropriate.
NRC Staff Response: • The following revision was made: "Protective eye wear will be worn by the surgeon and any personnel involved in the surgical procedure for protection of the eyes from possible splashing of radioactive material and exposure from beta radiation (if applicable)." • The model procedures provide acceptable procedures for responding to an emergency involving licensed material. Licensees may either adopt the model procedures or develop their own procedures to meet the requirements. • The model procedures provide acceptable procedures for responding to an emergency involving licensed material. Licensees may either adopt the model procedures or develop their own procedures to meet the requirements. However, RSO notification of radiological hazards associated with emergency surgery or autopsy is appropriate because the RSO is responsible for day-to-day oversight of the radiation safety program.		
Appendix O	Model Procedures for Ordering and Receiving Packages	Page O-1: Under Model Guidance, the NRC references "written records." This should be changed to permit electronic records as well as written records.
NRC Staff Response: The reference to "written" was deleted.		

Location	Subject	Comment
Appendix P	Model Procedure for Safely Opening Packages Containing Radioactive Material	• There are references in Appendix P that require immediate notification of the RSO (e.g., damaged package received, etc.). This should be less restrictive and permit notification of the RSO or DESIGNEE. • Page P-1, Item 4: "Monitor the external surfaces **and at 1 meter** for radiation levels..."

NRC Staff Response:

- The model procedures provide acceptable procedures for opening packages containing radioactive material. Licensees may either adopt the model procedures or develop their own procedures to meet the requirements. However, RSO notification of radiological hazards associated with leaking packages is appropriate since the RSO is responsible for day-to-day oversight of the radiation safety program.
- The existing guidance corresponds with the applicable wording in 10 CFR 20.1906(b)(2). Therefore, a revision is unnecessary.

Location	Subject	Comment
Appendix R	Model Procedure for Area Surveys	• Page R-1: Relocate the 1st paragraph (bullets under "Facilities and Equipment") to Page R-2 under "Contamination Surveys." • Page R-2, table R.1: Why is the trigger ambient dose rate for unrestricted areas 0.05 mR/hr (50 μR/hr); this is about the ambient background radiation level!? And assuming that this was indeed the NUREG intended level, there is then an inconsistency between: page R-1 "Radiation level surveys will consist of measurements with a survey meter sufficiently sensitive to detect 0.1 mR/hr." How then would one measure the trigger level of 0.05 mR/hr? • Also, the trigger levels outlined in Table R.1 "Ambient Dose Rate Trigger Levels" do not specify at what distance these readings should be obtained.

NRC Staff Response:

- We agree with the proposed revision.
- We agree that the suggested trigger level for unrestricted areas is too low. The model procedure was revised to indicate a trigger level of 0.1 mR/hr for unrestricted areas.
- NRC expects licensees to use good technique to perform ambient dose rate surveys. In general, the probe should be positioned close to the surface being measured without touching the surface.

Location	Subject	Comment
Appendix R	Model Procedure for Area Surveys	• Page R-3, 4th bullet: "The area will be either decontaminated, shielded, or posted and restricted from use if unable to decontaminate." This is misleading because 10 CFR 30.50(b)(i) requires 24 hour notification, as applicable, if an area is restricted to allow for decay. • Page R-4, Table R.2: The sample nuclides given are not comprehensive enough compared to what is used in the medical field today. For example, Y-90, Lu-177, and Sm-153 are not included. The limits in this table are more restrictive than those outlined in Table 2 "Recommended Action Levels For Removable Surface Contamination in Medical Institutions" and there is no justification for making these limits more restrictive. Why the change? • Table R.3 can be used for unrestricted areas and equipment. The NRC does not need to make the decontamination limits so restrictive for I-125. The material (I-125) is more benign than I-131 and the only reason it appears in the more restrictive category is that it has a longer half-life. This is unnecessary and should be taken into consideration before this guide is finalized.

NRC Staff Response:

- A statement was added to remind licensees of the reporting requirement in 10 CFR 30.50 for contamination events.
- Table R.2 was revised to include Y-90, Lu-177, and Sm-153 in the P-32, etc., category. Table R.2 was previously included in Regulatory Guide 10.8, Revision 2 (1987), as Table N-1. Table 2, "Recommended Action Levels For Removable Surface Contamination in Medical Institutions," is from Regulatory Guide 8.23, Revision 1 (1981). Both tables provide similar action levels for removable surface contamination and may be used by the licensee. However, because of the similarities and to reduce confusion, only one table was provided in the NUREG.
- We agree that the suggested trigger level documented in Table R.3 of 20 dpm/100 cm^2 set for I-125 and I-129 appears low. This value and other values in the table were chosen to be consistent with the values provided in guidance for release of facilities and equipment (Policy and Guidance Directive FC 83-23). However, consistent with the grouping used in Table R.2, I-125 was moved to be grouped with I-131. Additionally, transuranics and I-129 were deleted from this table, because medical licensees do not normally use transuranics or unsealed I-129.

Location	Subject	Comment
Appendix R	Model Procedure for Area Surveys	• Page R-5: The section on Alternate Survey Frequency is confusing and not user friendly. In the NRC's attempt to simplify the criteria for alternate survey frequencies, they have made it more complicated and unnecessarily so. What is the NRC's criteria for placing certain nuclides in the specific groups as outlined on page R-6? Also, there is no explanation of how the table is to be used, although those who are familiar with International Atomic Energy Agency Safety Series may recollect the way to use the data. • It is our strongest recommendation that Appendix R, "Model Procedure for Area Surveys," be withdrawn and redone. A technically comprehensive risk analysis should be performed to establish contamination limits based on the potential for byproduct material nuclides actually used in medical procedures to deliver dose to an individual.

NRC Staff Response:

- The alternate survey frequency was based on IAEA Safety Series 115. We agree that Table R.4 should be revised to exclude radionuclides that are not used in medicine. Additionally, a discussion on how to use the table was provided immediately under the title, "Alternate Survey Frequency."
- As discussed previously, we believe that NUREG-1556, Volume 9, is risk-related and performance-based. NRC recognizes the low risk associated with many licensed activities and the ability of medical licensees to develop safe procedures without direct NRC involvement.

Location	Subject	Comment
Appendix R	Model Procedure for Area Surveys	Unfortunately, the NRC has cited ambient dose and contamination limits that are unnecessarily low and/or impractical to measure in the real world. For example, how many medical programs would be capable of measuring external dose rates of 0.050 mrem/hour (50 prem/hour) in unrestricted areas? (This is the Ambient Dose Rate Trigger Level cited in Table RA) How many could adequately and efficiently measure the limit set in Table R.3 of 20 dpm/ 100 cm^2 set for I-125, I-129 and transuranics?
NRC Staff Response: We agree that the suggested trigger level in Table R.1 should be revised to 0.1 mR/hr for unrestricted areas. We also agree that the suggested trigger level documented in Table R.3 of 20 dpm/100 cm^2 set for I-125 and I-129 appears low. This value and other values in the table were chosen to be consistent with the values provided in guidance for release of facilities and equipment (Policy and Guidance Directive FC 83-23). However, consistent with the grouping used in Table R.2, I-125 was moved to be grouped with I-131. Additionally, transuranics and I-129 were deleted from this table, because medical licensees do not normally use transuranics or unsealed I-129.		

Location	Subject	Comment
Appendix R	Model Procedure for Area Surveys	• The primary purpose of limiting contamination is to prevent potential ingestion, inhalation or absorption of radioactivity by those working in a contaminated area or by those who contact contaminated materials; i.e. to prevent internal dose. The Part 20 regulatory limit of 0.02 mSv/hr for ambient dose rates within restricted areas is sufficient to require that contaminated materials be cleaned to the extent that those external dose rates are not exceeded where contamination is present. It is most unfortunate that footnote 6 of Table R.3 is inconsistent with the regulations of Part 20, in that it requires that the limit for radiation levels from surface contamination should be .002 mSv/hr average and 0.01 mSv/hr maximum at a distance of one centimeter (!) from the surface. This unnecessary "rachet-down" of the regulatory limit should be eliminated. • Is 1 % or 0.1 % of the allowable occupational dose conservative enough? If so, then surface contamination levels in the 100,000's of dpm would be acceptable for most nuclides. Allowable levels for fixed contamination could be even higher. Whatever limit(s) are set they should be based on a percentage of the ALI for a nuclide, not a number which "seems" like a good idea.

NRC Staff Response:

- The model procedures provide acceptable procedures for area surveys. Licensees may either adopt the model procedures or develop their own procedures to meet the requirements. Nonetheless, the rationale for using the values in Table R.3 is described above.
- As described in the *Federal Register* Notice dated November 18, 1998, Volume 63, Number 222, Pages 64132-64134, "Supplemental Information on the Implementation of the Final Rule on Radiological Criteria for License Termination," the criteria to replace the values in Policy and Guidance Directive FC83-23 need to be developed. Therefore, except for the minor changes described above, no change to Table R.3 has been made pending development of the final criteria.

Location	Subject	Comment
Appendix R	Model Procedure for Area Surveys	Given that the external ambient dose rate limit is met, then to what activity should one decontaminate for removable or fixed contamination to prevent possible internal dose? The table below lists a number of nuclides, some of which are common in medical facilities, others of which have value in facilities which also do biomedical research. The table lists the nuclide, the group (hazard classification?) into which the NRC has placed that nuclide in the table within Appendix R, the Annual Limit on Intake (ALI) for ingestion for that nuclide in both pCi and dpm, and the respective activities in dpm for the 100 mrem, 5 mrem and 0.5 mrem internal doses, based on the ALI. These dpm values should be kept in mind when reviewing Tables R.2 "Acceptable Surface Contamination Levels in Restricted Areas in dpm/100 cm^2" and R.3, "Acceptable Surface Contamination Levels in Unrestricted Areas in dpm/100 cm^2."
NRC Staff Response: We agree that the criteria to replace the values in Policy and Guidance Directive FC83-23 need to be developed, as described above. Therefore, except for the minor changes described previously, no change to Table R.3 has been made pending development of the final criteria. Additionally, the values in Table R.2 have not been revised at this time pending development of the final criteria.		

Nuclide	Group	ALI (pCi)	ALI (dpm)	2.0% ALI (dpm)	0.1 % ALI (dpm)	0.01% ALI (dpm)
			5000 mrem	**100 mrem**	**5 mrem**	**0.5 mrem**
H-3	4	80,000	1.776E+11	3,552,000,000	177,600,000	17,760,000
C-14	3	2,000	4.44E+09	88,800,000	4,440,000	444,000
P-32	3	600	1.33E+09	26,640,000	1,332,000	133,200
P-33	n/a	6,000	1.33E+10	266,400,000	13,320,000	1,332,000
S-35	3	10,000	2.22E+10	444,000,000	22,200,000	2,220,000
Cl-36	2	2,000	4.44E+09	88,800,000	4,440,000	444,000
Ca-45	2	2,000	4.44E+09	88,800,000	4,440,000	444,000
Cr-51	3	40,000	8.88E+10	1,776,000,000	88,800,000	8,880,000
Ni-63	3	9,000	2.00E+10	399,600,000	19,980,000	1,998,000
Ga-67	n/a	7,000	1.55E+10	310,800,000	15,540,000	1,554,000
Tc-99m	4/2	80,000	1.78E+11	3,552,000,000	177,600,000	17,760,000
I-125	n/a	40	8.88E+07	1,776,000	88,800	8,880
I-131	2	30	6.66E+07	1,332,000	66,600	6,660
Tl-201	3	20,000	4.44E+10	888,000,000	44,400,000	4,440,000

Location	Subject	Comment
Appendix S	Procedures for Developing, Maintaining, and Implementing Written Directives	• A great deal of detail specified in Appendix S is not necessary if the NRC changes 10 CFR 35. The NUREG should not be finalized until the revision to Part 35 is complete so that the required information is accurately reflected. • Page S-5: The section on Review of Administrations Requiring a Written Directive is confusing as written. The NRC should be less prescriptive.

NRC Staff Response:

- The final NUREG was revised to reflect the requirements from the final regulation.
- The existing language appears clear. The model procedures provide acceptable procedures for administrations that require a written directive. Licensees may either adopt the model procedures or develop their own procedures to meet the requirements.

Location	Subject	Comment
Appendix T	Model Procedures for Safe Use of Licensed Material	• Page T-1, 1st bullet: "wear lab coats or other protective clothing at all times in areas where radioactive materials are used." This is too restrictive. This would require anyone entering a laboratory where RAM is used to wear a lab coat. A lab coat only needs to be worn when working with RAM not when in RAM use area. Suggest: "Wear lab coats or other protective clothing **whenever working with radioactive material**." • Page T-1, 5th bullet: "do not store food ...in any area where licensed material is stored or used." This is too general, please define "area." Does it refer to an area that is used only to store RAM or does it refer to RAM stored in refrigerator located in a lab wherein RAM work is performed? • Page T-1, 7th bullet: Please delete this entire bullet, and replace with a general statement such as: "**Wear extremity dosimeters, if required, when handling radioactive material.**" All the examples of such instances is unnecessary. • Page T-1, 10th bullet: The decay method is not always applicable, per 10 CFR 30.50 (b).

NRC Staff Response:

- The model procedures provide acceptable procedures for safe use of licensed material. Licensees may either adopt the model procedures or develop their own procedures to meet the requirements. Furthermore, contamination may be present in areas where radioactive materials are used. Therefore, an individual may become contaminated by being present in an area where radioactive materials are used even if the individual is not using radioactive material. Therefore, no revision was made.
- The model procedures provide acceptable procedures for safe use of licensed material. Licensees may either adopt the model procedures or develop their own procedures to meet the requirements. Additionally, the proposed revision appears unnecessary because an area of use or storage may include a room or a refrigerator.
- We agree with the proposed revision and have incorporated the suggested change.
- The following revision of the tenth bullet on page T-1 was made, "...If necessary, decontaminate the area."

Location	Subject	Comment
Appendix X	Model Procedure for Waste Disposal by Decay-in-Storage, Generator Return, and Licensed Material Return	• Page X-1, 1st bullet: It is not within this NUREG guide's authority to prescribe how biomedical waste will be segregated for disposal, other than to ensure that radioactive waste is properly disposed. Segregation of biomedical waste is under the auspice of the licensee's Occupational Safety program. • Page X-1, 3rd bullet, 2nd item: "Check the radiation detection survey meter for proper operation **and current calibration status**." • Page X-1, 3rd bullet, 4th and 5th items: "Remove any shielding from around the container or generator column." ..."Monitor, at contact all surfaces of each individual container." What is the logic behind removing shielding and monitoring each individual container? Doing so may present a significant biological hazard. All containers, i.e., MPW boxes, syringe boxes, will provide some measure of shielding. Why is it inappropriate for this shielding to be advantageously used as an exposure reduction method, especially for short-lived biomedical radioactive material? • Page X-1, 3rd bullet, 7th item: "Discard as in-house waste only those containers that cannot be distinguished from background" What are considered to be the "containers"? – MPW boxes, syringe boxes? Does this conflict with items 4 and 5 above?

NRC Staff Response:

- The model procedures provide acceptable procedures for waste disposal. Licensees may either adopt the model procedures or develop their own procedures to meet the requirements.
- The suggested revision was added to the third bullet on page X-1.
- The shielding that is typically removed is lead that is separate from an inner plastic container (e.g., needle box, plastic bag). Therefore, the shielding can be removed without compromising the barrier to the biological hazard. Prior to disposal as non-radioactive waste, the shielding must be removed in order to confirm that the licensed material held for decay has decayed to background levels.
- "Container," as used here, may include trash bags full of waste, generator columns, or biohazard (needle) boxes. These examples were included in the NUREG.

Location	Subject	Comment
Appendix X	Model Procedure for Waste Disposal by Decay-in-Storage, Generator Return, and Licensed Material Return	Page X-1, 3rd bullet, 7th item: "Record the disposal date, ~~the radionuclides disposed,~~ the survey instrument used, ~~the background dose rate, the dose rate measured at the surface of each waste container,~~ and the name...." There is no need to include the radionuclide because it has decayed and no longer exists. There is also no need to document the background and surface dose rates, which will be at background radiation levels. The surveyor is responsible for ensuring that the proper disposal criteria are met; maintaining additional superfluous documentation is burdensome.
NRC Staff Response: Recording the radionuclide is a means of accounting for licensed material from "cradle to grave." Documenting the background and surface dose rates records which results were used to determine that the waste met DIS provisions for disposal. Therefore, no change was made in response to the proposed revision.		